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Representativeness of Patients Enrolled in a Primary Care Clinical Trial for Substance Use Disorders

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science at Virginia Commonwealth University.

by
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Abstract

REPRESENTATIVENESS OF PATIENTS ENROLLED IN A PRIMARY CARE CLINICAL TRIAL FOR SUBSTANCE USE DISORDERS

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Understanding the characteristics of research participants is crucial to ensuring sample representativeness and generalizability of findings to broader patient groups with substance use disorders. Using anonymous computer-administered health survey data, the present study had a unique opportunity to compare patients who chose to participate in an RCT for heavy/problem drinking or drug use (N=713; consenters) with those that chose not to participate (N=625; non-consenters). The sample was 40% male, 76% African American, and had a mean age of 45.2 years. Using multivariate regression, the most parsimonious model found older age, unemployment, prescription misuse, positive screen for drug problems (CAGE), having a grandmother with an alcohol problem, trouble falling asleep (past 30 days), health professional recommendation to go on a diet, and feeling unsafe due to a previous partner were all associated with consenting to participate. The present study provides benchmark data on sample representativeness in a clinical trial of SBIRT.

Representativeness of Patients Enrolled in a Primary Care Clinical Trial for Substance Use Disorders

Introduction

Randomized clinical trials (RCTs) are widely regarded as the gold standard for evaluating the efficacy of a treatment for a particular disorder. However, the conclusions drawn from an RCT are applicable in clinical settings only to the extent that the trial participants resemble the patient population of interest (Humphreys et al., 2013). Findings from RCTs with participants who meet rigorous criteria may not generalize to those with comorbid psychological disorders, substance abuse, or are homeless. This has been a long standing 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 Heath (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. Their inclusion was required except in situations where it would be inappropriate due to their health, the purpose of the research, or other circumstances pending NIH approval.

While this movement improved the representation of these groups, the "disconnect" between research and practice was still apparent, particularly in the field of substance abuse (Carroll & Rounsaville, 2003). Research has established that large proportions of individuals with substance use disorders cannot meet eligibility criteria for clinical trials and trial participants have also been found to be markedly different from

both community samples and treatment seekers (Humphreys et al., 2013). For example, the median clinical trial in the tobacco-dependence field has 12 exclusion criteria and approximately two thirds of smokers in the general population are ineligible under one or more of such criteria (Le Strat et al., 2011). Similarly for alcohol dependence, 79% of treatment-seeking individuals would be ineligible under at least one prevalent clinical trial criterion (Blanco et al., 2008), and African Americans are particularly underrepresented in such trials (Humphreys and Weisner, 2000; Humphreys et al., 2007). Since the 1970's, treatment outcome studies have become increasingly restrictive in their enrollment procedures (Humphreys et al., 2005). Participants in pharmacological and psychosocial treatments for substance dependence are fundamentally different from individuals receiving care for those disorders in real world treatment facilities (Humphreys et al., 2013). Moreover, this research is restricted to only those individuals who present for substance abuse treatment, which represents only 15% of individuals with a substance user disorder, leaving 85% of the population unstudied (Carroll et al., 2011; Institute of Medicine, 1990).

To access this larger patient population that does not present at specialty care clinics, intervention efforts have expanded to include medical care settings (e.g., emergency departments, primary care clinics) where such persons can be found (Bien et al., 1993). In this arena, clinical trials of brief interventions of as little as 15 minutes have been shown to be effective with reducing alcohol and other drug use (Bien et al., 1993; Hettema et al., 2005). Brief interventions aim to increase patient motivation to make positive behavior changes and typically consist of a healthcare professional providing assessment, feedback, information, advice, and self-help materials (Beich et al., 2002).

Brief interventions have similar efficacy to longer and more intensive interventions (Moyer et al., 2002; Burke et al., 2003), and not only produce short-term behavior change, but also longer-term, sustained reductions in risk behaviors (Fleming et al., 1997). Such interventions offer an exciting, new treatment approach, filling the gap between primary prevention and more intensive treatment services in a substance abuse group not served by existing community and hospital-based substance abuse treatment programs.

Historically, the effectiveness of brief interventions prompted the Institute of Medicine to recommend integrating service systems that link community-based screening and brief intervention services to assessment and referral activities, resulting in the development of a public health approach to substance abuse treatment know as screening, brief intervention, and referral to treatment (SBIRT) (Agerwala et al., 2012). SBIRT is an evidence-based practice that can be flexibly applied to a range of clinical care settings, providing the opportunity for early intervention with at-risk substance users, brief treatment for those with less severe SUDs, or referrals to specialized substance abuse treatment programs for those with higher severity (Agerwala et al., 2012). While SBIRT provides better access to a broader, more heterogeneous patient population, the same issues that impact RCTs in substance abuse treatment settings might also influence brief interventions research because not all such patients are willing to participate in clinical trials. This could decrease sample representativeness and investigator ability to generalize study findings.

Research on the factors associated with participation and nonparticipation in SBIRT trials is scarce. In part, this is because it is often difficult to even determine actual

rates of participation because researchers seldom report data on the size of the potential pool of subjects or the number willing to participate. Understanding the characteristics of research participants is crucial to better understand sample representativeness and generalizability of findings to broader patient groups with substance use disorders.

The purpose of the proposed study is to identify demographic and psychosocial variables associated with participation in a large primary care RCT of SBIRT for heavy/problem alcohol and/or drug use. The study utilizes screening data from a 4-arm RCT, which compared substance use outcomes at 1, 3, and 6 months post-intervention. The 4 treatment groups were: screening only (standard care control), assessment only, assessment plus computer-delivered brief intervention, and assessment plus therapist-delivered brief intervention. Participants were identified using a computer-administered anonymous health survey with embedded questions about alcohol and other drug use. Data was collected on a diverse range of variables including patient demographics, drug and alcohol use, family history of substance use, living environment and social supports. Using the health survey data from the N=1,338 individuals who met RCT criteria for heavy/problem substance use, the proposed study will compare individuals who enrolled in the study (N=713; consenters) to those who chose not to participate (N=625; non-consenters). Based on the RCT literature, the study will test the following hypotheses: 1) Non-white ethnic minorities will be less likely to participate compared to white individuals. 2) Individuals of lower socioeconomic status will be less likely to participate compared to those of a higher socioeconomic status. In addition, given the paucity of research on characteristics associated with research participation in similar settings,

univariate logistic regression will be used to identify other correlates of RCT study participation.

Review of the Literature

Brief History

National Institutes of Health

Inclusion of women and minorities in research is necessary in order to make valid inferences about health and disease across gender and minority groups (Bennett, 1993). Failure to include sufficiently diverse populations in trials leads to treatment protocols skewed toward a norm of middle-aged, white males. However, women and members of minority groups have historically been excluded from or underrepresented in clinical trials. To address this issue, Congress mandated that the National Institutes of Health (NIH) ensure that all federally funded clinical research include a valid analysis of treatment effects across gender and ethnic groups.

On June 10, 1993, President Bill Clinton signed into law the NIH Revitalization Act, which established guidelines for inclusion of women and minorities in clinical research (Freedman et al., 1995). Their inclusion was required except in situations where it would be inappropriate due to their health, the purpose of the research, or other circumstances pending NIH approval. Further, any NIH-funded clinical trial in which women or minority groups were included was required to provide a valid and thorough analysis of whether the intervention under study affected women or members of minority groups differently from other subjects in the trial. This NIH Act served as a major impetus for greater diversity and more representative research samples with findings

likely to have greater generalizability than previous research with more narrow and restricted samples.

Despites these laudable goals, the implementation of the NIH Revitalization Act also contributed to both scientific and practical concerns (Woolson et al., 1995). First, the Act failed to define "appropriate representation," leading to a wide array of interpretations based on the location of the study and the available population. For example, some trials are located in geographic locations in which the area served is relatively homogenous with regard to race/ethnicity. These investigators may be restricted in what representation they are able to achieve and may only be able to follow the guidelines of the Act by recruiting additional sites to increase the population mix. While such a strategy may be possible for a multicenter clinical trial, it may not be possible for a single-site investigation. Second, a clinical trial must balance the conflicting desires for homogeneity and heterogeneity (Bennett, 1993). In the ideal study, a cohort is homogenous enough to yield a high probability of learning whether a therapy is safe and effective, but also heterogeneous enough to ensure that the observed results are applicable beyond a narrowly defined subgroup. Maintaining this balance, while also achieving the "appropriate representation" mandated by the Act has been difficult for many researchers to achieve. Lastly, subgroup analyses, while conceptually important, are often impractical as the clinical trials are often underpowered to examine treatment effects within demographic subgroups. As a result, investigators must be cautious when interpreting differences in therapeutic response across gender or ethnic groups based on small sample sizes.

CONSORT Statement

In addition to the efforts to improve the representativeness of clinical research, strides were also being taken to improve the quality of both the methodology and reporting in clinical trials (Moher et al., 2001). The findings from randomized controlled trials (RCT) provide valuable information to clinicians and can directly influence patient care. Consumers of this research need to understand the design, methods, analysis, and generalizability of the trial in order to make informed judgments regarding the internal and external validity of the trial. This level of understanding is only possible with complete transparency from the authors. In the mid-1990s, an international group of clinical researchers, statisticians, epidemiologists, and biomedical editors published the Consolidated Standards of Reporting Trials (CONSORT) statement to help researchers improve the reporting of their study by use of a checklist and flow diagram (Begg et al., 1996).

The CONSORT statement provides guidance for all randomized clinical trials (RCT), but focuses on the 2-group parallel-design, as it is the type of trial most commonly reported (Moher et al., 2001). The checklist provides a list of 25 items to include in the methods, results, and discussion of an RCT report and identifies key pieces of information necessary to evaluate the internal and external validity of the study. The flow diagram provides information about how to present the progress of participants through each phase of the trial. It also provides valuable information about the original size of the sample, the number excluded from the study, attrition rates, the number of participants in each intervention group and whether the authors conducted an intention-to-treat analysis. These guidelines were intended to aid in the writing, reviewing, and assessing of reports on RCTs. The CONSORT statement received a great deal of support

following its publication and was adopted by a number of journals as criteria for publication. The CONSORT statement is an iterative document that has continually evolved with advances in research. The quality of reporting improved significantly with the adoption of the CONSORT guidelines.

Efficacy Versus Effectiveness

Despite these advances in clinical research, there was a disconnect between research and practice, which was particularly apparent in the treatment of drug abuse (Carroll & Rousaville, 2003). It became evident in the early 1980s that there was a lack of overlap between the interventions for alcohol dependence that had demonstrated efficacy and those routinely being used in alcohol treatment programs (Donovan et al., 2011). Similarly, very few empirically tested behavioral treatments for drug dependence were being used in substance abuse treatment programs, with many such programs using interventions that lacked empirical validation. This "gap" in the substance abuse field reflected a disconnect between clinical research, efficacy trials conducted primarily in academic centers, and the providers, who delivered the majority of treatments in community-based drug abuse treatment programs (Tai et al., 2011). Recognition of this disconnect introduced the push and pull between two approaches to clinical research: efficacy and effectiveness trials.

Efficacy trials are designed to maximize internal validity by randomly assigning patients to a new intervention or treatment, as well as a control condition intended to control for professional attention and other nonspecific elements of treatment. The setting of the trial, typically a research clinic, is also carefully controlled with an often artificial representation of community-based treatment settings. In contrast, effectiveness trials are

designed to maximize external validity by recruiting representative samples of patients from the community in order to generalize findings to the population of interest.

Table 1 summarizes the key characteristics of efficacy and effectiveness trials using the RE-AIM evaluation framework (Glawgow et al., 2003). Reach refers to the research participants and the representativeness of the obtained sample; efficacy or effectiveness pertains to the impact of an intervention on the particular outcome of interest; adoption refers to the organizations or settings that will conduct the given intervention under evaluation; implementation refers to the quality and consistency of the intervention; and maintenance refers to the extent to which the treatment becomes institutionalized in an organization following its evaluation.

Table 1.

Efficacy and Effectiveness Research Using RE-AIM Evaluation Framework

RE-AIM Issue	Efficacy Studies	Effectiveness Studies
Reach	Homogenous, highly motivated sample; exclude those with complications, other comorbid problems	Broad, heterogeneous, representative sample; often use a define population
Efficacy or effectiveness	Intensive specialized interventions that attempt to maximize effect size; very standardized; randomized designs	Brief, feasible interventions not requiring great expertise; adaptable to setting, randomized, time series, or quasi-experimental designs
Adoption	Usually 1 setting to reduce variability; settings with many resources and expert staff	Appeal to and work in multiple settings; able to be adapted to fit setting
Implementation	Implemented by research staff closely following specific protocol	Implemented by variety of different staff with competing demands, using adapted protocol
Maintenance and cost	Few or no issues; focus on individual level	Major issues; setting-level maintenance is as important as individual-level maintenance

The disconnect between research and practice occurs for two primary reasons: subject selection and how settings and contextual factors are treated (Glasgow et al., 2003). In a tightly controlled efficacy trial, only highly motivated, homogenous self-selected volunteers who do not have any complications or other comorbid conditions are eligible to participate. Following the study, the intervention is expected to translate to practice and be effective in a much more heterogeneous patient population, many of whom have comorbid conditions and may not volunteer for treatment. Secondly, efficacy studies typically control variance by restricting the setting to one set of circumstances (e.g., one particular clinic), while effectiveness studies attempt to understand the variation in outcomes across heterogeneous settings and delivery agents. Thus, interventions that are efficacious under highly specific conditions often fail to replicate across settings, conditions, and intervention agents in effectiveness research.

Clinical Trials Network

Development of CTN

In an effort to address this disconnect, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) jointly commissioned the Institute of Medicine (IOM) in 1997 to determine means by which interventions developed in academic settings could be translated more effectively into clinical practice (Tai et al., 2010). The IOM committee's report, "Bridging the gap between practice and research: Forging partnerships with community-based drug and alcohol treatment," provided recommendations to increase communication, interaction, and shared involvement of researchers and community-based

practitioners in both the development and implementation of interventions. Following these recommendations, NIDA established the National Drug Abuse Treatment Clinical Trials Network (CTN), whose mission was to improve the translation of science-based addiction treatments into community-based practice.

The CTN brought together academic researchers and community-based providers to develop and implement provider-informed clinical trials to be conducted in community-based drug treatment settings (Donovan et al., 2011). The partnership provided a reciprocal relationship where the researchers were able to address practice-relevant questions, while also fulfilling the practical needs of community-based treatment programs (CTPs). During the first decade of CTN research, the network supported 17 regional centers and the directors and clinical staff of affiliated community-based treatment programs (CTPs). The CTN Steering Committee served as the CTN's governing body to ensure consensus on central research and operational issues. Researchers and providers had equal representation with one principal investigator and one provider voting from each regional node. The infrastructure of the CTN fostered collaboration between researchers and treatment providers to both generate scientific findings and more directly inform clinical practice (Tai et al., 2010).

Bidirectional Partnerships

The bidirectional communication and collaboration within the CTN has resulted in study designs that meet the needs of both academic and clinical settings, increasing the likelihood that treatment providers will make use of research findings (Tai et al., 2010). Academic investigators trained to focus on scientific innovation and the validity of research methodology partner with providers focused on the quality of patient care, the

constraints of clinical budgets, and the challenges of implementing evidence-based treatments in clinical practice. This partnership can be challenging, often with conflicting views, but ultimately results in research innovation. The promise of this approach was evident in the first wave of CTN trials testing brief, simple-to-implement interventions including: 1) short-term buprenorphine/naloxone-aided opioid detoxification, 2) one-session Motivational Interviewing and three-session Motivational Enhancement therapies, and 3) low-cost contingency management programs. Efficacy trials of these treatments had demonstrated strong evidence for their utility, however these novel treatments faced resistance in acceptance and adoption in clinical practice that could be addressed with the CTN approach.

First, providers were reluctant to use pharmacotherapies in the treatment of addiction, so despite the evidence for buprenorphine, it was rarely used in practice (Saxon & McCarty, 2005). CTN trials had researchers at each Node work closely with staff at community treatment programs throughout protocol development and implementation to address important research and clinical questions. This collaborative approach demonstrated that treatment programs could use buprenorphine safely and effectively, creating early adopters that continued to use the buprenorphine in their clinical practice after the trial was completed. Second, there was a strong body of evidence supporting the use of motivational interviewing interventions (Martins & McNeil, 2009), however treatment providers reported that they could not be reimbursed for three individual sessions, decreasing its adoption in clinical practice. Thus, the CTN conducted two separate trials evaluating a one-session motivational interviewing intervention and a three-session motivational enhancement therapy intervention (Carroll

et al., 2002). Both trials demonstrated that enhanced motivation improved treatment retention, and more importantly, the importance of clinical supervision in ensuring effective treatment delivery (Ball et al., 2007; Carroll et al., 2006). This literature promoted the recognition and acceptance of rigorous MI training and supervision in the field. Lastly, the efficacy of motivational incentives (contingency management) in the treatment of substance use disorders had been well established in opioid, marijuana, alcohol, cocaine and methamphetamine dependent patients (Bickel et al., 1997; Budney et al., 2000; Higgins et al., 2002; Knapp et al., 2007; Petry et al., 2000). However, motivational incentives were not adopted by substance abuse treatment providers due to concerns about the potential negative consequences of providing tangible reinforcements to patients with substance use disorders and the associated costs of offering incentives in clinics with limited budgets (Kellogg et al., 2005; Higgins et al., 2008). In an effort to overcome these barriers to adoption, the CTN developed two clinical trials testing low-cost motivational incentive interventions. The findings from these trials and the cost-effectiveness analyses demonstrated the feasibility and clinical utility of this intervention. Similar to the CTN buprenorphine clinical trials, participating treatment providers promoted the wider use of motivational incentives following the clinical trials. These seminal studies demonstrated that collaboration between researchers and treatment providers generated scientific findings that translated to clinical practice.

Representativeness

Consistent with this overarching goal of linking research and practice, the CTN also aimed to conduct clinical trials among more diverse samples of substance users than may be typical of efficacy trials (Carroll et al., 2002). CTN protocols have aimed to

minimize barriers to treatment entry and broaden study inclusion/exclusion criteria in order to attract highly heterogeneous samples. For example, many CTN trials limited study inclusion criteria to age (18 years or older) and seeking outpatient treatment for a substance use disorder. In these RCTs, participants would be excluded only if they required medical detoxification or were psychiatrically or medically unstable to the point that outpatient treatment was not feasible. CTN trials have been open to a wide variety of substance users with a wide range of co-occurring psychiatric, legal, employment, and social problems, better reflecting the 15% of persons with substance use disorders who enter specialty care.

The multisite approach of the CTN also facilitated obtaining more heterogeneous samples by recruiting across clinics to access a diverse patient population (Covey et al., 2011). The multisite method facilitates faster recruitment, increases study enrollment, and achieves better variability in the characteristics of study participants. Further, the patient populations of different sites can be assessed to obtain samples that would not be possible with a single site trial (Burlew et al., 2011). For example, certain community treatment programs (CTPs) serve higher rates of ethnic minorities and would enable the trial to obtain a more representative sample. These sites would be advantageous in that they could recruit from their natural caseloads and also have more experience working with ethnic minorities. Single site trials with lower rates of ethnic minorities in their caseloads are forced to recruit outside of their enrollment streams, which is difficult not only logistically, but also often requires further training of clinical staff to be effective with populations outside of their usual scope of expertise.

Recruitment

In addition to the representativeness of clinical trials, particular attention also started to focus on the method through which participants were obtained. Research indicated that there can be significant differences in sample characteristics as a function of recruitment method in clinical trials of smokers (Harris et al., 2003), depressed elderly patients (Stack et al., 1995), and Alzheimer's disease patients (Andersen et al., 2010). Smokers recruited with reactive methods (disseminating information that asked people to call a study hotline) reported significantly higher levels of education and income, better health, and significantly lower indicators of depression and life hassles, compared with those recruited with proactive methods (in-person appeals by research staff and health care providers) (Harris et al., 2003). In depressed elderly patients, referred patients included a higher proportion of African Americans and had a lower level of education, fewer economic resources, and higher chronic medical burden (Stack et al., 1995). Patients recruited with proactive methods had been in their depressive episode longer than referred patients at the time of study entry and were 3.4 time more likely to have experienced a severe trauma during the 6 months that preceded the onset of their depressive symptoms. Lastly, Alzheimer's patients recruited with reactive methods (e.g., mail) were younger and more self-reliant male patients with a higher MMSE sum score, while older women with more severe cognitive impairment were recruited from general practice with proactive methods. Taken together, evidence began to support the notion that the method in which patients are recruited could influence the characteristics of the obtained sample.

Multiple forms of recruitment are routinely used in effectiveness studies, particularly with samples that are difficult to recruit, as is often the case in substance

abuse research. A CTN study by Winhusen et al (2012) investigated this concept by comparing two recruitment methods used at one site of a multi-site trial evaluating Seeking Safety (SS), relative to Women's Health Education (WHE) for women with co-occurring PTSD and substance use disorders. Participants recruited through newspaper advertising, relative to those from substance abuse clinic intakes, had significantly higher levels of baseline drug use and a higher percent met DSM-IV-TR criteria for PTSD. In turn, the results suggested that the effectiveness of the intervention was greater for this more severe sample relative to those recruited directly from the treatment program. Thus, recruitment efforts in clinical research may impact sample composition as well as treatment effects.

Where Are We Now?

While the CTN is committed to bridging the gap between research and practice and has made large strides, it is still subject to some concerns. Even if a representative sample can be obtained in the CTN, it is still only representative of the population of substance users seeking treatment. Only a minority of individuals diagnosed with substance use disorders access specialty care (Carroll et al., 2011). Many individuals with substance use issues never present at a treatment facility due to a multitude of issues, including limited access to care, lack of treatment financing, scarcity of trained clinicians, lack of interest in seeking treatment, and stigma. According to SAMHSA's National Survey on Drug Use and Health (NSDUH), 22.7 million persons 12 years and older needed treatment for an illicit drug or alcohol use problem in 2013 (SAMHSA, 2013). Of these individuals, 2.5 million (11 percent of those who needed treatment) received treatment at a specialty facility (i.e. hospital, drug or alcohol rehabilitation or mental

health center). Thus, while the CTN created an infrastructure of research partnering with community-based treatment centers, this research remains focused only on 15% of substance users in the community; namely those who present for treatment.

Although the generalizability associated with multisite effectiveness trials is exciting, the higher levels of heterogeneity in the sample also introduce a variety of practical problems (Carroll et al., 2002). Treatment manuals are typically written targeting specific types of substance users, however the patient populations across sites often vary in disease severity, treatment readiness, treatment resistance, or other individual characteristics that could influence treatment response. Additionally, the variations among sites can also occur in ways that could obscure outcomes. By only assessing aggregate results, specific effects in particular subgroups can be masked. Examining site differences and how they may influence the experimental treatment has been advocated as a means of ensuring validity and avoiding misrepresentation of findings, but it is rarely done in practice. Such challenges, have left investigators with the task of setting eligibility criteria broad enough to ensure adequate enrollment of a demographically diverse group of patients, while also taking into consideration the costs associated with larger samples, and maintaining sufficient power to detect treatment effects and readily interpretable results (Humphreys et al., 2007). Thus, despite the CTN's efforts to recruit more representative samples for substance abuse treatment research, most of the protocols still sacrifice generalizability for the sake of high internal validity (Carroll et al., 2011).

In turn, the representativeness of this research remains a concern, particularly with regard to minorities due to ethnic differences in the factors related to substance use

(Burlew et al., 2011). For example, cultural factors result in ethnic differences in drug histories (Shillington & Clapp, 2003), specific drugs used (Moselhy & Telfer, 2002), as well as overall attitudes about mental health treatment (Buser, 2009). Further, cultural differences in both the spirituality and acculturation to substance use attitudes may also influence treatment response. Thus, when certain ethnic groups are underrepresented, it impedes the development of effective treatments to reduce health disparities in substance use. As of February 2011, the CTN had enrolled 2,700 (22%) African American, 2,071 (17%) Latino, 179 (1%) American Indian/Alaska Native, 56 (<1%) Asian/Pacific Islander, and 1,575 (13%) other/multirace participants across 30 clinical trials. Overall, CTN retention rates for ethnic minorities have been similar to the retention rates for Whites, however they have varied widely across trials (Burlew et al., 2011). CTN trials that included higher rates of ethnic minorities included community treatment programs (CTPs) that served a larger proportion of ethnic minorities. CTPs with lower rates of ethnic minorities in their caseloads often need to recruit outside their typical enrollment streams, making it difficult to obtain a representative sample. Eligibility criteria remain a large determinant of investigator ability to recruit ethnic minorities, with the two CTN trials having the lowest number of ethnic minorities also listing more stringent eligibility criteria. The inclusion criteria from one of these studies required that participants not only be using prescription opiates, but also meet criteria for attention-deficit/hyperactivity disorder (ADHD) and smoke more than 10 cigarettes per day. Lastly, the two trials with the lowest ethnic minority enrollment were medication trials, whereas the trials with the higher numbers of ethnic minorities were behavioral trials. This suggests that the type of trial may also influence the recruitment of ethnic minorities.

Overall, the multisite approach of the CTN has made great strides in clinical research and offered the first step toward effectiveness trials in the field of substance abuse. However, over the course of the CTN, the aforementioned challenges of generalizability, recruitment, and the overall representativeness of this research have become a cause for concern. In an effort to address these issues, there may be a tendency for CTN sites to be selected for new trials based upon track records of successful (more rapid) recruitment in prior research trials rather than for their representativeness of the larger population of community-based treatment programs (Nunes et al., 2010). This approach is understandable as it ensures the integrity and feasibility of the research. However, the selected community-based treatment programs may become more like research clinics over time once again listing their representativeness of the target population and undermining the original mission of the CTN. Taken together, such factors have contributed to the expansion of clinical trials to include new health care settings such as primary and specialty medical care with a focus on screening, brief intervention, and referral to treatment (SBIRT).

SBIRT

Epidemiology of Substance Use Disorders

An estimated 24.6 million Americans aged 12 or older report using illicit drugs in the past month and 60.1 million report binge drinking over that same time interval (SAMHSA, 2013). Only 11% of those in need of treatment received care at a specialty facility, and of those not receiving treatment, 96% felt they were not in need of such services. Thus, the majority of persons with heavy/problem alcohol or drug use are not actively engaged in traditional substance abuse treatment. While the majority of such

persons are not likely to seek substance abuse treatment, they are more likely to seek medical care for a variety of health problems associated with heavy drug use (Mertens, et al., 2003). Research has shown that between 8 and 25% of primary care patients meet criteria for heavy/problem substance use (Mertens et al., 2003; Brown et al., 2001; Fleming et al., 1997). Taken together, primary care clinics were identified as an ideal setting for education and intervention with this at- risk population of heavy/problem substance users.

Overview

Screening, brief intervention, and referral to treatment (SBIRT) is an evidence-based practice used to identify, reduce, and prevent problematic substance use (Agerwala & McCance-Katz, 2012). SBIRT is a public health approach to the delivery of early intervention and treatment services that can be applied in a range of clinical care settings including hospital emergency settings, primary care centers, office- and clinic-based practices, and other community based centers, providing access to patient populations that may not present in traditional treatment facilities. SBIRT interventions can provide brief treatment for those with less severe SUDs or referrals to specialized care for those with more severe substance use.

SBIRT is comprised of three stages: screening, brief intervention, and referral to treatment (Agerwala & McCance-Katz, 2012). Screening involves a brief assessment to evaluate current severity of substance use and identifies the appropriate level of treatment. For patients who screen positive for problem or risky substance use, screening is followed by brief intervention with a focus on preventing the progression to a full-blown SUD. Brief interventions refer to any time-limited effort, typically 1-2 brief

conversations, to increase patient awareness regarding their substance use and motivation toward behavioral change. Referral to treatment facilitates access to care for patients identified as already having a substance-related health condition or a suspected use disorder that warrants a formal diagnosis and requires specialty treatment.

History of SBIRT

The current model of SBIRT began in the 1980s as reliable screening tools, such as the Michigan Alcohol Screening Test (Selzer, 1971), the CAGE (Ewing, 1984), and the Drug Abuse Screening Test (Skinner, 1982) became available (see Babor & Kadden, 2005 for review). These tools were required in order to provide rapid methods of universal screening for substance use. The development of such screening tools facilitated the integration of substance abuse treatment services into primary care settings due to the new ability to identify patients in need of such services. The impetus for the integration of substance abuse services into primary care grew from findings that patients who received encouragement from their health care providers to cut down or stop drinking had lower levels of alcohol consumption and decreased mortality associated with heavy drinking compared to controls who were informed by letter to be restrictive with their alcohol consumption (Kristenson et al., 1983). Similarly, brief physician advice was found to significantly help patients stop smoking cigarettes compared to usual care controls (Russell, Stapleton & Hajek, 1988).

The goal of brief interventions is to increase patient motivation to make positive behavior changes. Brief interventions typically consist of six elements summarized by the acronym FRAMES: Feedback, Responsibility, Advice, Menu, Empathy, and Self-efficacy (Miller & Sanchez, 1994). The health care provider provides feedback on the

patient's current substance use, advises on how to quit or cut down, offers a menu of options for change, and supports the patient's self-efficacy to enact those changes. Brief interventions were shown to be similar in efficacy to longer and more intensive interventions (Moyer et al., 2002; Burke et al., 2003), and were associated with not only short-term but also longer-term behavior change, with sustained reductions in risk behaviors (Fleming et al., 1997). Brief interventions of as little as 15 minutes were shown to be effective with reductions in alcohol and other drug use (Bien et al., 1993; Hettema et al., 2005). They offered an exciting, new treatment approach that filled the gap between primary prevention and more intensive treatment services by identifying patients that may never present for specialty care. Recognizing the potential of SBIRT from these seminal studies, the World Health Organization (WHO) focused on how to best implement screening and brief intervention in primary care settings, and more broadly, how to integrate SBIRT into health care systems around the world (Agerwala & McCance-Katz, 2012).

Such efforts began in emergency departments (ED), which serve as the safety net of care in the United States, and as a result, become the point of access to health care for millions of Americans (Bernstein et al., 2009). In 2011, approximately 2.5 million ED visits were related to drug misuse or abuse (Drug Abuse Warning Network, 2011). Understanding that a visit may appear in more than one group, approximately 51 percent of these visits involved illicit drugs, 51 percent involved nonmedical use of pharmaceuticals, and 25 percent involved drugs combined with alcohol. Thus, the ED is a primary setting to access substance users that otherwise might not present for treatment. Further, patients with substance use and mental health conditions visit the ED with

greater frequency compared to patients without these disorders (Bernstein et al., 2009). This data, combined with the findings of research in the CTN, prompted further expansion of the SBIRT intervention into numerous primary care settings, and has become the standard of care in recent years.

Affordable Care Act

Implementation of SBIRT in primary care settings comes at a pivotal time in health care reform. Historically, public substance abuse treatment services have operated independent of the overall health care system, utilizing separate administration, funding, and service delivery systems (Buck, 2011). The 2009 National Survey on Drug and Health reported that respondents in inpatient treatment for alcohol or drug problems in the US population age twelve and older were 50 percent more likely to identify a rehabilitation facility as their source of inpatient care, compared to a hospital (SAMHSA, 2009). Outpatient care followed the same access pattern with treatment in a rehabilitation facility two-and-a-half times more frequent than treatment in a private doctor's office. Most of these specialty clinics are stand-alone nonprofit or government operated facilities that carry daily caseloads of fifty or fewer patients (Buck, 2011). More than three-quarters of the funding for these specialty clinics comes from public sources, compared to less than half for all other health care (Levit et al., 2008). Further, staff members who have limited professional training and supervision typically deliver the treatment (Roman, Ducharme & Knudsen, 2006; Willenbring, 2010; McLellan & Meyers, 2004). Less than half of the treatment facilities that rely on public funding employ counselors trained at the master's degree level and a third do not have a physician either on staff or contract. The Affordable Care Act of 2010, coupled with declines in state general

revenue spending, marked the beginning of systemic change in the financing, structure, and delivery of substance abuse treatment services.

The Affordable Care Act includes several provisions that affect substance abuse treatment services, most notably; the law greatly expanded the number of insured people with substance abuse disorders (Buck, 2011). A provision within the law mandates that people who meet 133 percent of the federal poverty level are eligible to receive Medicaid. This expansion was estimated to nearly double the number of nonelderly childless adults with behavioral health disorders in Medicaid, because this population is primarily low-income and uninsured. The majority of people with behavioral health disorders gaining this coverage are likely to be those with mental health conditions, however this provision will likely have the greatest impact for those individuals with substance abuse disorders. Medicaid or Medicare eligibility is available for nonelderly childless adults with serious mental illness through Supplemental Security Income or Social Security Disability, both of which require a determination of disability. However, eligibility is typically denied for those with substance use disorders if their drug or alcohol abuse is the primary cause of the disability. Under the Affordable Care Act, this barrier to insurance coverage will no longer exist, and all individuals whose income meets criteria are eligible.

The expansion of Medicaid coverage resulted in further medicalization of public substance abuse treatment and greater participation from physicians, psychologists, nurse practitioners, and other health professionals (Buck, 2011). Medicaid outpatient services typically require physician-directed services for reimbursement. Substance abuse treatment services that consist primarily of education and psychosocial support provided

by peer or lay counselors do not constitute medical assistance and in isolation, may not qualify for Medicaid reimbursement. Thus, health centers are uniquely positioned to respond to the increased demand for substance abuse treatment, resulting in a shift away from residential and stand-alone programs toward integrating these services into the mainstream of general health care. Under this health reform, addiction is recognized as a chronic relapsing disorder that should be treated in primary care, providing patients with better access to substance abuse services that are medically based and person-centered. More patients will be presenting in primary care to receive substance abuse treatment, providing easier access to this patient population for both treatment and research efforts.

Who Participates?

As substance abuse research expands to the primary care setting, it provides access to the 85% of patients that do not seek treatment. While in many ways access to this population seems to increase generalizability, the fact is we do not know how many of them will consent to research participation, and how, if at all, those consenting may differ from the population of interest. Although the CONSORT statement promotes better tracking of participants, the majority of studies are not reporting the characteristics of participants that are eligible for the trial but do not elect to participate, which is important information to consider when interpreting the findings, as well as when translating research to clinical practice. For example, a study conducted by Berstein et al. (2011), investigating the efficacy of a brief smoking cessation intervention among emergency department patients, had 663 patients eligible to participate of whom N=325 declined. The study included a consort diagram listing the reasons for declining to participate including: refused to participate, admitted, not interested in quitting or already quit, and

other. Although this is important information to include, it does not provide any insight into patient demographics and how they may differ from the sample under investigation. This is nearly half of the eligible participant pool that was excluded from analyses. This information is particularly important now that substance abuse services are being integrated in primary care. In specialty care, everyone presenting for treatment has a substance related issue, however in primary care, understanding the larger pool of eligible participants begins with screening and only a subset go on to participate in the trial. This information enables better understanding of patients' reasons for declining research participation (e.g., stigma) and the characteristics that may influence those reasons (e.g., demographics, substance use severity).

There are many factors that can contribute to nonparticipation in clinical trials including, the treatment options not being of interest, lack of time, research burden being too great, lack of transportation and/or child care. However, there may be additional factors at play in substance abuse research due to the strict regulations, fear of legal consequences, and stigma associated with substance use (Andreae et al., 2016). Stigma surrounding certain behaviors (e.g., substance use during pregnancy) and groups (e.g., injection drug users) are widely accepted, culturally endorsed and supported by criminal law (Livingston et al., 2012). The stigma surrounding substance use is also unique in that people with this condition are often perceived as having personal control over their illness, and thus more likely to be held responsible and blamed (Schomerus et al., 2011; Albrecht, Walker & Levy, 1982; Corrigan, Kuwabara & O'Shaughnessy, 2009). Stigma has been well established as a significant barrier for accessing health care and substance use treatment services (Radcliffe & Stevens, 2008; Copeland, 1997; Digiusto & Treloar,

2007; Keyes et al., 2010; Semple, Grant & Patterson, 2005). Health-care providers may hold negative beliefs about people with substance use disorders, including that they abuse the system with drug seeking behavior, overuse system resources, are not vested in their own health, and fail to adhere to doctor recommendations (Mak et al., 2007; Henderson, Stacy & Dohan, 2008). Thus, individuals with substance use disorders may conceal their use in order to avoid this stigma. There have not been any studies on the role of stigma in SBIRT research, however the fact that the substance users presenting in primary care are the 85% not seeking treatment for their substance use, it is likely that stigma may also play a role in their willingness to participate in clinical research. Understanding how these factors influence research participation is critical in order to tailor research efforts to target these populations.

To date, we found no published studies investigating differences among individuals that accept and decline participation in SBIRT research. However, trends in research participation have emerged from more general clinical trials in medical based settings. Historically, African Americans and other minority populations have participated in clinical trials far less when compared to whites, even after the NIH Revitalization Act of 1993 (Durant et al., 2011; Anwuri et al., 2013). Racial differences in the willingness to participate in medical research have been largely attributed to mistrust of researchers and health care providers. Rooted in historical events such as the US Public Health Services Syphilis Study at Tuskegee (Tuskegee Study) among African Americans and efforts to sterilize American Indians, mistrust has been associated with the perception that research will benefit Whites of the research institution and not people of color, a fear of purposeful mistreatment, and the perception that by signing the

informed consent they are relinquishing their rights and providing the researcher with legal protection against any harm that may be inflicted on the participants (George et al., 2014). Other well-established barriers for minority populations include a lack of informational access about research opportunities, a fear of discrimination from health insurance companies that may result from participating in health research, and a fear of deportation.

Another factor that has consistently been associated with decreased research participation is low socioeconomic status (Unger et al., 2013; Ford et al., 2008; Sateren et al., 2002; Guiliano et al., 2000). Regardless of race or ethnicity, low SES (e.g., educational attainment, income, employment status, insurance coverage) has consistently been shown to have a negative impact on clinical research participation. This has largely been attributed to individuals of lower socioeconomic status having limited access to health care, resulting in low rates of prevention and diagnostic procedures, and higher dependence on public hospitals where physicians are less likely to be involved in clinical research (Giuliano et al., 2000). Second, low SES patients are more likely to rely on Medicare and Medicaid insurance and coverage of costs associated with participation in a clinical trial is inconsistent and often denied. Further, there can be ethnical concerns associated with recruiting low SES patients and patients without health insurance because if an abnormality or problem is detected, these patients may not have adequate resources to receive follow-up care.

Beyond these characteristics, little is known about what other factors may be associated with participation in clinical research. This information provides insight into potential differences between individuals that choose to partake in research compared to

those that do not, however the screening information is so limited, that in a typical trial, little is known beyond the age, gender, race, and level of substance use. Thus, it is difficult to gain a complete understanding of how these two groups may differ because individuals that choose not to participate are never given a comprehensive screener.

Sampling

Gaining a better understanding of how individuals that agree to participate in research differ from those that do not is valuable information because sampling can directly influence the outcome of the study. Understanding the characteristics of individuals that participate in research is critical to making meaning out of the study findings. Interventions can vary in their effectiveness based on the characteristics of the sample under investigation. For example, evidence for the efficacy of brief interventions for alcohol use disorders on the milder end of the severity spectrum is well established (Kaner, et al., 2007; Jonas et al., 2012; D'Onofrio et al., 2012). However, brief interventions have been found to be less effective in dependent drinkers who may benefit from more specialized and intensive treatment (Bogenshutz et al., 2014; Gentilello et al., 1999).

Research findings have also been found to vary as a result of demographic characteristics such as gender and age. The overall evidence suggests that brief alcohol interventions are equally effective in men and women (Ballesteros et al., 2004; Whitlock et al., 2004; Bertholet et al., 2005), however most of the literature to date has focused primarily on male drinkers or not reported the data disaggregated by sex (Moyer et al., 2002; Kaner et al., 2007). Research studies that have included women in their analyses have yielded mixed results thus far, suggesting that brief interventions may not be

consistently helpful to women (Chang, 2002). Further, although brief interventions for alcohol-related disorders appear to be effective in adults aged eighteen and over, the findings at either end of the age spectrum are less conclusive. Research conducted primarily in US college settings has suggested that the effects of brief interventions are less long-lived in young adults, and there is insufficient evidence on BI effectiveness in either adolescent (Kaner et al., 2007; Jackson et al., 2010; Latimer et al., 2010) or older adult populations (Kaner et al., 2007; Jonas et al., 2012).

Lastly, little consideration has been given to the influence of socioeconomic status on effectiveness of brief interventions (Littlejohn, 2006; Gordon et al., 2007; Jackson al., 2010), and a number of reviews have noted the tendency for studies to either omit ethnic minorities or that they are poorly reported when included, often neither giving the breakdown of participants nor analyzing them separately (Gorden et al., 2007; Whitlock et al., 2004; Kaner et al., 2007; Jackson et al., 2010; Jonas et al., 2012). There has also been a lack of conclusive evidence on the use of brief interventions in patients with co-morbid medical or psychiatric conditions, as these individuals are typically screened out to minimize the heterogeneity of the study sample. Thus, the sample plays a pivotal role in the study findings. Research needs to be meaningful to the general population. Gaining a better understanding of fundamental differences between individuals that participate in research would provide insight into the populations we are studying and provide information of value to both researchers and clinicians.

Statement of the Problem and Hypotheses

Randomized clinical trials (RCTs) are widely regarded as the gold standard for evaluating the efficacy of treatment for a particular disorder. However, there is still an

apparent disconnect between research and practice, particularly in the field of substance abuse (Carroll & Rounsaville, 2003). This is due in part to the fact that participants in pharmacological and psychosocial treatments for substance dependence are fundamentally different from individuals receiving care for those disorders in real world treatment facilities due to strict exclusion criteria and limited minority participation (Humphrey et al., 2013; Humphreys, 2003; Humphreys et al., 2007). Moreover, this research is only targeting the 15% of substance users that actually present for specialty care, leaving 85% of the population unstudied (Institute of Medicine, 1990).

In an effort to identify and serve this larger patient population that does not present for substance abuse treatment, intervention efforts expanded to focus on medical care settings (e.g., emergency departments, primary care clinics), such efforts contributed to the development of a public health approach to substance abuse treatment: screening, brief intervention, and referral to treatment (SBIRT) (Agerwala et al., 2012). Although SBIRT provides better access to this patient population, the same issues that impact RCTs in substance abuse treatment settings are also likely to influence brief interventions. SBIRT provides better access to a broader, more heterogeneous patient population, however not all such patients are willing to participate in SBIRT research, which might decrease sample representativeness and investigator ability to generalize study findings. Research on the factors associated with participation and nonparticipation in SBIRT trials is scarce and it is often difficult to even determine actual rates of participation because published results often do not report on such data.

The present study identified demographic and psychosocial variables associated with participation in a large primary care RCT of SBIRT targeting heavy/problem alcohol

and/or drug use. The study utilized anonymous, computer-administered health survey data in which patients who screened positive for heavy/problem substance use were randomized to one of four treatment groups: screening only, assessment only, assessment plus computer-delivered brief intervention, and assessment plus therapist-delivered brief intervention. To our knowledge, there have not been any other studies investigating predictors of research participation within this patient population. Based on findings for participants enrolled more broadly in clinical trials research, the study tested the following hypotheses: 1) Non-white ethnic minorities would be less likely to participate compared to white individuals. 2) Individuals of lower socioeconomic status would be less likely to participate compared to those of a higher socioeconomic status. In addition, given the paucity of research on other characteristics associated with research participation in similar settings, univariate logistic regression was used to identify additional demographic, clinical and psychosocial correlates of RCT study participation.

Methods

Participants

Participants were drawn from a data base containing N = 4,552 primary care patients who completed an anonymous, computer-delivered health survey. From this pool, the present study selected the N=1,338 individuals who met RCT inclusion criteria for heavy/problem alcohol and/or other drug use. Specifically, study compared individuals who consented to participate in the SBIRT RCT (N=713; consenters) and those that chose not to participate (N=625; non-consenters).

Inclusion criteria. Adults who were 18 years of age or older, seeking primary care at VCUHS, residing within the hospital catchment area (City of Richmond and

surrounding counties), able to speak and understand English, indicated they were not currently enrolled in alcohol/drug treatment (inpatient, residential, outpatient, methadone maintenance, therapeutic community), and who met criteria for heavy/problem alcohol and/or drug use were eligible for the RCT.

Heavy/problem alcohol use was defined as either: 1) A score greater than or equal to 2 on the CAGE (for men) or greater than 2 on the T-ACE (for women) combined with self-report of consuming more than 14 drinks/week (men) or 7 drinks/week (women) over the past 30 days; or 2) Self-reported consumption of more than 4 drinks (men) or more than 3 drinks (women) on at least two occasions in the past 30 days.

Heavy/problem drug use was defined in the following 3 ways: 1) A score of greater than or equal to 1 on Drug CAGE combined with a report of drug use on at least one occasion in the past 30 days; 2) using one or more illicit drugs at least 2 days/week in the past 30 days; or 3) using prescribed medications in contraindicated ways (e.g., taking more than prescribed, using someone else's prescription, getting medications from more than one health provider) on at least 2 occasions in the past 30 days.

Exclusion criteria. Patients were ineligible for the RCT if they presented with a serious psychiatric or cognitive impairment that prevented them from giving true informed consent.

The study was approved by Virginia Commonwealth University's Institutional Review Board under "Project COMP: A Randomized Clinical Trial, " protocol number HM13196 and all participants provided informed consent.

Design and Procedures

Participants were recruited from the VCUHS primary care and OB/GYN clinic waiting rooms by trained study staff. Potential participants were approached at random in the lobby area while they were waiting to see their practitioner. They were asked if they were at least 18 years of age, and if they answered yes, RAs proceeded to tell them about an anonymous health behavior study (Health Cheq) and asked if they wanted to learn more about the study. If yes, the patient was escorted to a private area adjacent to the clinic waiting room, where the research assistant briefly told them about the study. Specifically, they were told that the study sought to learn more about the health behaviors of patients in the VCUHS Primary Care Clinic and OB/GYN Clinic. It was a computer-directed survey that focused on health behaviors, including sleep, mood, diet and exercise, smoking, drinking, and medication/drug use. They were informed that the survey would only take 20 minutes and they would receive $10 for their time and effort. They were also informed that based on their responses to these questions, they may have the opportunity to participate in another study that the research assistant would tell them more about, if they were eligible.

Patients who met inclusion criteria and provided informed consent were taken to a quiet area proximal to the waiting room. The research assistant logged them onto a touch-screen computer and left the area while the patient completed the survey. A mobile three-dimensional cartoon character (Peedy the Parrot) read each item for the participant, acted as narrator, and guided them throughout the process. Participants listened to Peedy via headphones to ensure privacy. Upon completion, each participant was given a $10 gift card for their time while the computer determined whether the patient met eligibility criteria for the SBIRT randomized clinical trial (RCT). Participants who screened

positive for heavy/problem substance use were informed that they qualified for the RCT and were invited to participate. They were informed that if they chose to participate in the RCT the computer would assign them, by chance, to one of four study groups. Depending upon the group they were assigned to, the research would take anywhere from 5 to 40 additional minutes on that day and then they would be scheduled for 20-40 minute follow-up research visits 1, 3, and 6 months post enrollment. They were informed that regardless of group assignment, they would receive $20 for participating, and could earn an additional $120 for completing the three follow-up sessions. They were reminded that their answers to survey questions and their participation in the study would be confidential. If the participant consented to the RCT, they were randomized to one of the four study groups: true control, assessment only, assessment plus computer-delivered brief intervention, and assessment plus therapist-delivered brief intervention. If the participant was not eligible, they were compensated and thanked for their participation.

Measures

The survey was administered using a laptop computer and participants were oriented to the computer and study procedures by the RA. Participants could use either the touchscreen or keyboard/mouse to proceed through the survey. All answers were provided by choosing responses from a list or by touching a visual analogue scale. Pleasing and relevant graphics changed with each screen to maintain interest. The program was completely private and required no computer or reading literacy. Participants wore headphones that enabled them to listen to Peedy the Parrot who served as narrator and guided them through the Health Cheq survey. Alcohol and drug use items to determine RCT eligibility were embedded within the larger Health survey that focused

on demographics, general health, mood and anxiety, smoking, nutrition and other health behaviors and concerns. This was done to minimize any stigma associated with completing a screener about substance use.

Demographic Characteristics and Health Behaviors. Demographic variables included age, race, education, employment, marital status, current living situation, social services, and insurance coverage. Items addressing general health behaviors and concerns were also included such as exercise, nutrition, diet, as well as computer literacy.

Smoking Behavior. Quantity and frequency of recent tobacco use were assessed with items from the Fagerstom Test for Nicotine Dependence (Heatherton et al., 1991). The items assessed a range of current smoking behaviors including the number of cigarettes smoked per day, the amount of time after waking in the morning to first cigarette, and which cigarette would be the most difficult to give up. The Fagerstrom Test for Nicotine Dependence has demonstrated high reliability, as well as validity when using cotinine as a criterion variable (Pomerleau et al., 1994). Lifetime tobacco use was assessed with items from the National Survey on Drug Use and Health (Wells et al., 2006). The items quantified lifetime cigarette smoking with questions such as: "Which statement best describes your smoking behavior over your lifetime?" with 3 response options (1 = *100 or more cigarettes* and 3 = *I have never smoked cigarettes*). The tobacco items were the first substance use questions presented to the patients in order to give them a chance to get familiar with the software and the program narrator, Peedy the Parrot, while reporting on a health behavior that is less socially stigmatizing than heavy/problem alcohol or drug use.

Physical and Emotional Health. Participants were presented with a range of medical conditions related to addiction (e.g., chronic obstructive pulmonary disease (COPD), arthritis, hepatitis, liver disease, pancreatitis) and asked whether they had ever received a diagnosis for any of the listed conditions. They were also asked about the reason for their current medical visit (e.g., yearly check-up, new health problem, ongoing health problem) and, in general, how would they rate their overall health on a 5 point scale (1 = *excellent* and 5 = *poor*).

Patient Health Questionnaire (PHQ-9). Depressive symptoms were assessed using items from the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer & Williams, 2001). The PHQ-9 is a 9-item depression measure, which scores each of the 9 DSM-IV criteria on a 4-point scale (0 = *not at all* and 3 = *nearly every day*). The diagnostic validity of the PHQ-9 has been well established in the primary care setting with 2 studies involving 3,000 patients in 8 primary care clinics and 3,000 patients in 7 obstetrics-gynecology clinics (Sptizer et al., 1999; Spitzer et al., 2000). The PHQ-9 is half the length of other depression measures, while still maintaining comparable sensitivity (88%) and specificity (88%).

General Anxiety Disorder (GAD-7). Anxiety symptoms were assessed using items from the Generalized Anxiety Disorder Screener (GAD-7) (Spitzer et al, 2006). The GAD-7 is a 7-item anxiety measure, which scores the 7 core symptoms of generalized anxiety disorder on a 4-point scale (0 = *not at all* and 3 = *nearly every day*). The diagnostic validity of the GAD-7 has been well established in the primary care setting with a criterion-standard study performed in 15 primary clinics in the United States demonstrating good consistency between GAD-7 diagnosis and those of

independent mental health professionals (sensitivity, 89%; specificity, 82%) (Spitzer et al, 2006).

Sleep Behavior. Sleep behavior was assessed using items from the Insomnia Severity Index (Bastian, Vallieres & Morin, 2001). Participants were asked to rate if they had difficulty falling asleep, staying asleep, or problems waking up too early on a 5 point scale (1 = *none* and 5 = *very severe*). The Insomnia Severity Index corresponds with the DSM-IV criteria for insomnia, and measures perceptions of symptom severity, distress, and daytime impairment. The diagnostic validity of the measure has been well established in distinguishing individuals diagnosed with primary insomnia from good sleeper controls (sensitivity, 94%; specificity 94%) (Smith & Wegener, 2003). The use of prescription medications for sleep was also assessed with an item from the Pittsburgh Sleep Quality Index (PSQI) asking participants if they took any medication to help them sleep in the past 30 days, and if so, how often did they take this medication as a sleep aid on a 4 point scale (1 = *daily* and 4 = *less than twice per week*) (Buysse et al., 1989). This measure has also demonstrated diagnostic validity in distinguishing good and poor sleepers (sensitivity, 89.6%; specificity, 86.5%).

Alcohol Use and Problems. Items were included to assess the quantity and frequency of recent use (past 30 days), as well as binge drinking. NIAAA guidelines were used to define drinking behaviors, with heavy drinking defined as more than 7 drinks per week for women and more than 14 drinks per week for men (NIAAA, 2009). Binge drinking corresponded to having more than 4 drinks on a single occasion for women and more than 5 drinks on a single occasion for men (NIAAA, 2009).

T-ACE. The T-ACE, a brief 4-item questionnaire was used to detect risky drinking in women. The T-ACE was developed in 1989 (Sokol, Martier, & Ager) to detect alcohol consumption in women that could potentially harm the fetus. The T-ACE, a mnemonic that stands for Tolerance, Annoyed, Cut down, and Eye opener, uses identical questions for three of the four questions from the CAGE, but replaces the Guilt question with a Tolerance (High) question: (How many drinks does it take to make you feel *high*?). Thus, the main difference between the two measures is that the CAGE asks whether the patient felt guilty about drinking, while the T-ACE asks how many drinks it takes to make the patient feel high (Tolerance). The reason for this difference is that Sokol and colleagues (1989) found that the tolerance question, when added to the CAGE, showed that all items, with the exclusion of feeling bad or guilty, contributed significantly to the indication of risk drinking during pregnancy. Since the tolerance question carried more weight, developers assigned a score of 2 for the tolerance question. Thus, two points are assigned when a woman reports needing over two drinks in order to feel the intoxicating effects of alcohol or to feel "high." A score of 1 was assigned for each of the ACE questions. Therefore, scores range from 0 to 5. The present study used a cut-point of ≥ 2 on the T-ACE to predict risk drinking (Sokol, et al., 1989).

CAGE. While it can be used for males and females, the present study used the alcohol CAGE to detect problem drinking in men (Ewing & Rouse, 1970). CAGE is a mnemonic that stands for Cut down, Annoyed, Guilty, and Eye opener, and was originally standardized with a sample of White men. The four CAGE questions are: 1) Have you ever felt you should *Cut down* on your drinking?, 2) Have people *Annoyed* you by criticizing your drinking?, 3) Have you ever felt bad or *Guilty* about your drinking?,

and 4) Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (*Eye opener*)? Each affirmative response receives one point with total scores ranging from zero to four. A cut-off of ≥ 2 points on the CAGE is used as an indication of problem drinking (Mayfield, et al., 1974). CAGE has demonstrated high test-retest reliability and adequate correlations (0.48-0.70) with other screening instruments (Dhalla & Kopec, 2007). The questionnaire has been well established as a valid tool for detecting alcohol abuse in primary care patients (sensitivity, 71%; specificity, 91%).

Recreational/Illicit Use and Problems. Participants were presented with a list of various classes of drugs (modified from the CIDI drug module) (Ustun et al., 1997) and asked to check which drugs they used regularly (e.g., three or more times per week). The list included marijuana, cocaine, stimulants, inhalants, heroin, and hallucinogens. For those drugs endorsed, they were asked about their frequency of use in the past 30 days, including how many days they used as well as their average use per week.

Drug CAGE. Other drug use was assessed using the same question format as the original CAGE but was adapted to focus on other drug use: 1) Have you ever felt you should *Cut down* on your drug use?, 2) Have people *Annoyed* you by criticizing your drug use?, 3) Have you ever felt bad or *Guilty* about your drug use?, and 4) Have you ever used drugs first thing in the morning (*Eye opener*)? (Ewing & Rouse, 1970). Each affirmative response receives one point with total scores ranging from zero to four. A cut-off of ≥ 1 points on the Drug CAGE is used as an indication of substance abuse.

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. Patients were asked the frequency of their prescription misuse in the past 30 days, as well as what types of medications were misused from the following list: sleeping medicines, sedative medicines, stimulant medicines, stimulant medicines, and pain medicines.

Family History of Alcohol and Drug Problems. Participants were asked to report any problem alcohol or drug use of first-degree relatives and grandparents. Participants were also asked if they were living with someone who currently has a problem with drugs and/or alcohol with options yes/no/I don't know (McLellan et al., 1992).

Partner Violence Screen. The 3-item Partner Violence Screen was included to assess two dimensions of partner violence: physical violence and perceived safety (Feldhaus et al., 1997). Physical violence was assessed by asking," Have you been hit, kicked, punched, or otherwise hurt by someone within the past year?" with yes/no option. Two questions assessed perceived safety by asking, "Do you feel safe in your current relationship?" and "Is there a partner from a previous relationship who is making you feel unsafe now?" with yes/no options. Three studies have assessed the sensitivity and specificity of the PVS (sensitivity, 35%-71%; specificity, 80%-94%) (Feldhaus et al., 1997; Mills, Avegno & Haydel, 2006; MacMillan et al., 2009), and although it has demonstrated a wide range of sensitivity, it serves as a brief screen for identifying partner violence in the primary care setting.

Data Analysis Plan

Statistical analyses were performed with SPSS version 24 (SPSS Inc., Chicago, IL, USA). First, descriptive statistics were run for demographic data including gender, age, race, and ethnicity. Next, two study hypotheses were tested using univariate logistic regression for race and socioeconomic status, with insurance status, employment and education level serving as proxies for SES. For race, it was hypothesized that non-white ethnic minorities would be less likely to participate compared to white individuals. For socioeconomic status, it was hypothesized that individuals of lower socioeconomic status would be less likely to participate compared to those of a higher socioeconomic status

Univariate logistic regression was also used to identify other 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, including physical violence in the past year, feeling unsafe in current relationships, and drug use in current living environments. Significance was set at 0.05 for all univariate analyses; however, any variables reaching a significance level of <0.2, 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 issues of 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 Hossmer 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. Given the computer directed nature of the survey; rates of missing data were very low. The data was treated as is, with any case with missing values excluded from the analyses.

Results

Demographics. Demographic characteristics of consenters and non-consenters are summarized in Table 2, with variables eligible for inclusion in the multivariate analysis shown in italics. The first hypothesis that non-white ethnic minorities would be less likely to participate compared to white individuals was not supported. The two groups did not significantly differ in race; approximately three-fourths of both consenters and non-consenters were African American (77% and 75%, respectively), $\chi^2(1, N = 1{,}338) = 6.37$, $p = 0.59$. The second hypothesis, that individuals of lower socioeconomic status would be less likely to participate compared to those of higher socioeconomic status, was also not supported. The two groups endorsed similar levels of educational attainment, with nearly one-third of non-consenters endorsing less than high school and 26% of consenters, $\chi^2(2, N = 1{,}023) = 5.00$, $p = 0.08$. While the two groups did differ on both employment and insurance status, both differences were not in the hypothesized direction. Instead, individuals of lower socioeconomic status were more likely to consent, and over half of consenters were unemployed (51%) as compared to 41% of non-consenters, $\chi^2(5, N = 1{,}047) = 19.90$, $p = .001$. For health insurance, while nearly twice as many non-consenters reported private insurance (11%) as consenters (6%), three-fourths of consenters as compared to two-thirds of non-consenters reported the Virginia Coordinated Care Program (VCC), a program providing access to affordable health care

for uninsured individuals in Richmond (71% and 64%, respectively), $\chi^2(4, N = 1,047) = 15.39$, $p = 0.009$.

When other demographic variables were examined, consenters and non-consenters did not differ on age or gender. Both groups were in their mid-40's, 45.3 (*SD* = 10.8) and 45.1 (*SD* = 11.7) years, respectively, t (1336) = .26, $p = 0.79$, and over one-third of both groups were male (39% of consenters and 41% of non-consenters), $\chi^2(1, N = 1,338) = .21$, $p = 0.66$. The two groups did differ on marital status; with over half of non-consenters (51%) compared to 45% of consenters classified as single, $\chi^2(4, N = 1,046) = 9.72$, $p = 0.04$.

Table 2.

Demographic Characteristics of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (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)	
Education			*0.08*
Less than high school	26% (139)	30% (143)	
Grade 12 or GED	39% (212)	41% (193)	
Some college and beyond	36% (195)	30% (141)	
Employment Status			*0.001**
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)	
Health Insurance			*0.009**
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)	
Marital Status			*0.04**
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)	

Alcohol and Smoking. The alcohol and tobacco use characteristics of the two groups are summarized in Table 3. Consenters and non-consenters did not differ on a measure of tobacco use, with over three-fourths of consenters (79%) and 81% of non-consenters having ever smoked in their lifetime, $\chi^2(1, N = 1,335) = 0.78$, $p = 0.38$. Nearly two-thirds of each group were current smokers (60% consenters and 61% non-consenters), $\chi^2(1, N = 1,338) = 1.91$, $p = 0.39$.

For alcohol, the two groups differed only on binge drinking, with 71% of consenters reporting at least one recent binge episode compared to 78% of non-consenters, $\chi^2(1, N = 1,336) = 8.79$, $p = 0.003$. When males and females were examined separately, however, this difference was found only for males, (83% and 72%, respectively), $\chi^2(1, N = 535)$ 9.48, $p = 0.002$, and not females. No differences were found in prevalence of alcohol problems by CAGE (males) or T-ACE (females) screening tools.

Table 3.

Alcohol and Smoking of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
Tobacco Use			
Ever Smoked (Lifetime)	79% (564)	81% (507)	0.38
Current Smoker	59% (422)	61% (384)	0.39
Alcohol Use			
Binge Drinking (Past 30 days)			
Overall	71% (503)	78% (484)	*0.003*

Males	72% (202/281)	83% (211/254)	*0.002*
Females	70% (301/432)	73% (272/371)	0.21
Positive Alcohol Screen			
Overall	50% (353)	46% (286)	*0.18*
Men CAGE	41% (116/281)	39% (100/254)	0.65
Women T-ACE	56% (237/432)	44% (186/371)	*0.19*

Recreational/Illicit Use and Problems. Recreational and illicit drug use for the two groups are summarized in Table 4. Consenters were more likely to report recent recreational drug use (past 30 days) than non-consenters (36% and 26%, respectively), $\chi^2(1, N = 1{,}338) = 16.83$, $p < 0.001$. Similarly, consenters were more likely to screen CAGE positive for drugs than non-consenters (29% and 17%, respectively), $\chi^2(1, N = 1{,}337) = 26.51$, $p < 0.001$. Further, consenters reported using recreational drugs more days in the past month ($M = 5.09$, $SD = 9.71$), $t\ (1330) = 3.19$, $p = 0.001$, as well per week compared to non-consenters ($M = 1.39$, $SD = 2.35$), $t\ (1336) = 3.11$, $p = 0.002$.

Prescription Drug Misuse. Prescription drug misuse rates and characteristics are also shown in Table 4, with consenters more likely to endorse recent prescription drug misuse than non-consenters (27% and 17%, respectively), $\chi^2(1, N = 1{,}337) = 17.78$, $p < 0.001$. When specific symptoms of misuse were examined, consenters were more likely to endorse three of the four behaviors. That is, they were more likely than non-consenters to report taking more pills than prescribed, $\chi^2(1, N = 1{,}338) = 18.95$, $p < 0.001$, taking pills more often than prescribed, $\chi^2(1, N = 1{,}338) = 17.55$, $p < 0.001$, and using someone else's prescription, $\chi^2(1, N = 1{,}338) = 18.56$, $p < 0.001$.

Table 4.

Recreational/Illicit Use and Problems of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value

Recreational Drug Use Past 30 days	36% (258)	26% (161)	*<0.001**
Drug CAGE	29% (209)	17% (108)	*<0.001**
Days (Past 30) Used Recreational Drugs	5.09 (9.71)	3.52 (8.33)	*<0.001**
Days/Week (Past 30) Used Recreational Drugs	1.39 (2.35)	1.01 (2.10)	*0.002**
Rx Drug Misuse (past 30 days)	27% (190)	17% (108)	*<0.001**
More pills than prescribed	16% (113)	10% (63)	*<0.001**
More often than prescribed	12% (85)	6% (40)	*<0.001**
Used someone else's Rx	13% (91)	7% (42)	*<0.001**
Got Rx from more than one MD	2% (14)	2% (13)	0.88

Family History of Alcohol and Drug Problems. Family history of alcohol or drug problems in first and second degree relatives are show in Table 5. A subset of group comparisons found consenters were more likely than non-consenters to report alcohol problems for their biological mother, $\chi^2(1, N = 1{,}336) = 7.88$, $p = 0.005$, father, $\chi^2(1, N = 1{,}336) = 4.57$, $p = 0.03$, maternal and/or paternal grandmother, $\chi^2(1, N = 1{,}338) = 8.62$, $p = 0.003$, and maternal and/or paternal grandfather, $\chi^2(1, N = 1{,}338) = 4.19$, $p = 0.04$. Further, the two groups differed in parental density of alcohol problem patterns (no history, either parent, or both parents), with over half of non-consenters reporting no parental alcohol problems (54%) as compared to 46% of consenters, $\chi^2(2, N = 1{,}336) = 9.72$, $p = 0.008$.

For other drug problems, the same group comparisons of consenters and non-consenters yielded only one significant difference. That is, consenters were more likely to report drug problems in their biological fathers than non-consenters, $\chi^2(1, N = 1{,}337) = 5.58$, $p = 0.02$.

Table 5.

Family History of Alcohol and Drug Problems of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value

Alcohol Use			
Mother	21% (150)	15% (94)	*0.005**
Father	46% (331)	41% (253)	*0.03**
Grandmother	13% (91)	8% (49)	*0.003**
Grandfather	20% (140)	15% (96)	*0.04**
Parental Density			*0.008**
No history	46% (330)	54% (337)	
One parent	40% (285)	36% (225)	
Both parents	14% (98)	10% (61)	
Drug Use			
Mother	10% (69)	9% (57)	0.74
Father	15% (109)	11% (68)	*0.02**
Grandmother	2% (16)	1% (8)	*0.19*
Grandfather	3% (19)	2% (12)	0.37

Medical Conditions. Medical conditions for consenters and non-consenters are summarized in Table 6. Overall, there were no group differences, with the exception of hepatitis, which was endorsed by a higher percentage of consenters compared to non-consenters (14% and 10%, respectively), $\chi^2(1, N = 1{,}338) = 3.84$, $p = 0.05$. The two groups also did not differ in the number of medical diagnoses reported ($M = 1.24$, $SD = 1.28$) for consenters compared to non-consenters ($M = 1.13$, $SD = 1.06$), $t\ (1336) = 1.85$, $p = 0.06$.

Table 6.

Medical Conditions of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
COPD	11% (81)	10% (63)	0.45
Liver Disease	5% (32)	4% (24)	0.56
Hepatitis	14% (98)	10% (64)	*0.05**
Heart Disease	12% (88)	10% (63)	*0.19*
High Blood Pressure	55% (392)	51% (320)	*0.17*
Pancreatitis	2% (17)	2% (12)	0.56
High Cholesterol	26% (183)	26% (164)	0.81
Mean Number of Conditions	1.24 (1.18)	1.14 (1.06)	*0.06*

Sleep Behavior. Sleep behavior measures, including overall sleep quality ratings and medication use reports by consenters and non-consenters are summarized in Table 7. Quality of sleep ratings differed, with non-consenters more likely than consenters to report good/very good sleep (32% and 24%, respectively) and consenters more likely than non-consenters to report poor sleep quality (36% and 29%, respectively), $\chi^2(3, N = 1{,}338) = 17.12$, $p = 0.002$. Similarly, consenters were more likely to report trouble falling asleep, $\chi^2(1, N = 1{,}338) = 16.87$, $p = <0.001$, and staying asleep, $\chi^2(1, N = 1{,}338) = 8.08$, $p = 0.02$, than non-consenters. The same pattern was seen for sleep medication use, with nearly one-third of consenters using prescription medications for sleep (30%) as compared to one-fourth of non-consenters (25%), $\chi^2(3, N = 1{,}338) = 17.75$, $p = <0.001$.

Table 7.

Sleep Behavior of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
Sleep Quality			*0.002**
Poor	36% (257)	29% (179)	
Fair	40% (288)	39% (244)	
Good	18% (126)	25% (156)	
Very Good	6% (42)	7% (44)	
Sleep Problems			
Trouble Falling	72% (514)	62% (388)	*<0.001**
Trouble Staying	72% (516)	66% (410)	*0.02**
Sleep Medications	49% (349)	38% (237)	*<0.001**
Sleep Aids			*<0.001**
None	51% (364)	62% (388)	
Rx Only	30% (216)	25% (155)	
Non-Rx Only	13% (89)	9% (59)	
Both	6% (44)	4% (23)	

Mental Health-Related Conditions. Consenter and non-consenter self-reports of mental health problems and related conditions (e.g., migraines, chronic pain) are

summarized in Table 8. Group differences were found for all four conditions, with consenters more likely than non-consenters to endorse problems with anxiety, $\chi^2(1, N = 1,338) = 10.61$, $p = 0.001$, depression, $\chi^2(1, N = 1,338) = 19.17$, $p = <0.001$, migraines, $\chi^2(1, N = 1,338) = 4.62$, $p = 0.03$, and chronic pain, $\chi^2(1, N = 1,338) = 6.37$, $p = 0.01$. Mean number of conditions was also higher in consenters ($M = 1.39$, $SD = 1.28$) than non-consenters ($M = 1.08$, $SD = 1.16$), $t\ (1336) = 4.65$, $p < 0.001$

Table 8.

Mental Health-Related Conditions of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
Anxiety	39% (275)	30% (188)	*0.001**
Depression	48% (340)	36% (224)	*<0.001**
Migraine	16% (111)	11% (72)	*0.03**
Chronic Pain	37% (267)	31% (193)	*0.01**
Mean Number of Conditions	1.39 (1.28)	1.08 (1.16)	*<0.001**

Health Behaviors. Physical health behaviors for the two patient groups are summarized in Table 9. Overall, consenters and non-consenters reported similar amounts of physical activity, $\chi^2(3, N = 1,335) = 4.92$, $p = 0.18$. However, consenters indicated they spent a larger proportion of each day in sedentary activities compared to non-consenters, $\chi^2(3, N = 1,334) = 10.88$, $p = 0.01$. Further, consenters were more likely to report having received a recommendation from a health professional to go on a diet compared to non-consenters, $\chi^2(1, N = 1,336) = 7.64$, $p = 0.006$.

Table 9.

Health Behaviors of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
Physical Activity (Past 30 Days)			*0.18*

Rarely	24% (169)	25% (158)	
Some Light/Moderate Not Every Week	23% (165)	27% (168)	
Light/Moderate Every Week	36% (254)	33% (206)	
30 minutes or more/day, 5+ days	18% (125)	15% (90)	
Average hours/day at desk, watching TV or playing video games			*0.01**
0-2 hours	34% (244)	40% (247)	
3-5 hours	26% (184)	29% (178)	
6-8 hours	14% (102)	12% (77)	
More than 8	26% (183)	19% (119)	
Health professional recommendation to go on a diet	45% (319)	37% (233)	*0.006**

Other Risk Factors. Other risk factors, including physical violence in the past year, feeling unsafe in current relationships, and drug use in current living environment are summarized in Table 10. There was no significant group difference in reports of feeling unsafe in current relationship, 6% of consenters compared to 7% of non-consenters, $\chi^2(2, N = 1,337) = 3.07$, $p = 0.38$. However, consenters reported higher rates of physical violence, with 18% reporting violence in the past year compared to 13% of non-consenters, $\chi^2(1, N = 1,336) = 5.27$, $p = 0.02$. Similarly, nearly twice as many consenters as non-consenters reported that a previous partner was making them feel unsafe, $\chi^2(1, N = 1,338) = 8.64$, $p = 0.003$. Lastly, twice as many consenters reported living with someone who currently had a drug problem compared to non-consenters, $\chi^2(2, N = 1,338) = 15.33$, $p = <0.001$.

Table 10.

Other Risk Factors of Consenters and Non-Consenters

Variable	Consenters (N=713)	Non-Consenters (N=625)	P value
Unsafe Current Relationship	6% (43)	7% (44)	0.38
Physical Violence (past year)	18% (129)	13% (84)	*0.02**

Previous partner make feel unsafe	9% (62)	5% (29)	*0.003**
Living with Someone with Drug Problem	12% (82)	6% (39)	*<0.001**

Multivariate Analysis

All of the variables included in the univariate analyses are summarized in Table 11, with the variables selected for the multivariate italicized. The backward elimination included 30 iterations before arriving at the parsimonious model of predictors of research participation. As shown in Table 12, older age, being unemployed or on disability, taking medications more often than prescribed, positive screen for drug problems (CAGE), having a grandmother with an alcohol problem, trouble falling asleep (past 30 days), health professional recommendation to go on a diet, and feeling unsafe due to a previous partner were all associated with consenting to participate in the SBIRT RCT. Participants with ≤ high school degree, as well as those who were employed or retired was associated with declining study participation. 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.

Table 11.

Variables Included in Multivariate Logistic Regression

Demographics	**Substance Use**	**Family History**

Age *Gender* *Race* *Education* *Employment* *Health Insurance* *Marital Status*	Tobacco Use (Lifetime and Current Status) *Binge Drinking (Past 30 days)* *Positive Alcohol Screen (T-ACE & CAGE)* *Recreational Drug Use (Past 30 days)* *Positive Drug CAGE* *Days (Past 30) Rec. Drug Use* Days/Week (Past 30) Rec. Drug Use *Prescription Drug Misuse* *More polls than prescribed* *More often than prescribed* *Used someone else's Rx*		Alcohol *Mother* *Father* *Grandmother* *Grandfather* Parental Density Drug Use Mother *Father* *Grandmother* Grandfather
Sleep Behavior	**Physical Health**	**Mental Health**	**Other Risk Factors**
Sleep Quality *Sleep Problems* *Sleep Aids*	COPD Liver Disease Hepatitis Heart Disease High Blood Pressure Pancreatitis High Cholesterol *# of Conditions* *Physical Activity (Past 30 Days)* *Sedentary Activities* *Rec. to go on a diet*	*Anxiety* *Depression* *Migraine* *Chronic Pain* # of Conditions	Unsafe Current Relationship *Physical Violence (past year)* *Previous partner make feel unsafe* *Living with someone with a drug problem*

Table 12.

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	
Less than high school	-0.429	0.176	0.015	0.65 (0.46, 0.92)
Grade 12 or GED	-0.268	0.158	0.089	0.77 (0.56, 1.04)
Employment			0.016	
Full Time	-0.288	0.411	0.484	0.75 (0.34, 1.68)
Part Time	-0.051	0.410	0.902	0.95 (0.43, 2.12)
On disability	0.222	0.416	0.593	1.25 (0.55, 2.82)
Retired	-0.653	0.516	0.206	0.52 (0.19, 1.43)
Unemployed	0.258	0.391	0.510	1.29 (0.60, 2.79)
% Positive Drug Cage	0.680	0.165	<0.001	1.97 (1.43, 2.73)
Taking prescriptions	0.535	0.244	0.028	1.71 (1.06, 2.75)

more often than prescribed				
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 go on a diet	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)

Discussion

The purpose of the present study was to identify demographic and psychosocial variables associated with participation in a large primary care RCT of SBIRT targeting heavy/problem alcohol and/or drug use. The study analyzed anonymous, computer-administered health survey data through which eligible primary care patients for the RCT were identified. Using the N=1,338 patients who met RCT criteria and were invited to participate in the clinical trial, the present study compared those who consented to participate in the SBIRT RCT (N=713; consenters) with those that chose not to participate (N=625; non-consenters). First, based on existing literature, two hypotheses about demographic variables associated with research participation, were tested. Second, univariate logistic regression was used to identify additional demographic and psychosocial correlates of consent to RCT participation. Third, variables significant in univariate analyses at the $p < 0.2$ level were examined, using multivariate logistic regression to determine the most parsimonious model to predict patient consent to participate in a RCT targeting heavy/problem alcohol or drug use.

Summary of Findings

Present study findings did not support either of the two proposed hypotheses. Non-white ethnic minorities were not less likely to participate compared to white individuals. Further, individuals of lower socioeconomic status were not less likely to consent compared to those of higher socioeconomic status. There was no significant difference in racial distribution across the two groups, and with the exception of educational attainment, group differences in SES-related variables were in a direction opposite to what was predicted, with consenters more likely to be unemployed and receiving medical services through the Virginia Coordinated Care Program (VCC) compared to non-consenters. Additional univariate analyses of demographic variables found no differences in age, gender, or education between consenters and non-consenters.

When psychosocial factors and physical concerns were examined, consenters endorsed both a larger number and more severe problems across multiple domains. Specifically, consenters were more likely to report sleep disturbance as well as symptoms of anxiety, depression, migraines, and chronic pain than non-consenters. They also spent more time each day in sedentary activities and were more likely to have received a recommendation from a health professional to go on a diet. A larger proportion of consenters also resided with someone who had a drug problem, experienced an episode of physical violence (past year) and had a previous partner who was making them feel unsafe.

Alcohol and other drug use measures were of particular interest, as they contributed to the criteria for RCT qualification. Consenters were more likely than non-consenters to report recent and more frequent drug use, prescription drug misuse and

binge drinking. Further, consenters were more likely to endorse a family history of substance use than non-consenters.

Using multivariate regression analysis, the most parsimonious model predicting consent to RCT participation included nine variables. Eight of these variables were associated with consent to RCT participation, including: older age, being unemployed or on disability, taking medications more often than prescribed, positive screen for drug problems (CAGE), having a grandmother with an alcohol problem, trouble falling asleep (past 30 days), health professional recommendation to go on a diet, and feeling unsafe due to a previous partner. In addition, the model found ≤ high school degree, as well as being employed or retired to be associated with the decision not to participate in the RCT. In addition, the model found ≤ high school degree, as well as being employed or retired to be associated with the decision not to participate in the RCT. The model as a whole explained between 7.2% (Cox & Snell R Square) and 9.6% (Nagelkerke R Square) of the variance, and correctly classified 59.2% of cases.

Discussion of Findings

Hypothesis One. Present study findings do not support the first hypothesis. Non-white ethnic minorities were not less likely to participate compared to white individuals. Historically, African Americans and other minority populations have participated in clinical trials far less when compared to whites due to mistrust of researchers and health care providers, as well as a lack of informational access to research opportunities (Durant et al., 2011; Anwuri et al., 2013; George et al., 2014). As an urban primary care clinic that treats many indigent persons in the catchment area, perhaps present study findings reflect a clinical network where African Americans feel more comfortable to participate

in research and one that educates and informs patients about diverse research opportunities. A review conducted by Wendler et al. (2005) suggested that the low rates of minority participation in research are not a reflection of minorities being less willing to participate, but instead is a result of structural barriers to accessing research opportunities and biased recruitment strategies (Wendler et al., 2005). The present study findings are consistent with this research, suggesting that when given the opportunity, ethnic minorities are willing to participate.

Hypothesis Two. The present study also did not support the second hypothesis. Individuals of lower socioeconomic status were not less likely to consent compared to those of a higher socioeconomic status, and in most cases, the findings were contrary to what was predicted. That is, consenters were more likely to be unemployed or on disability than non-consenters. Similarly, consenters were more likely to be part of the Virginia Coordinated Care (VCC) program, while non-consenters were more likely to have private insurance. Previous research has suggested that low SES has a negative impact on clinical participation due to limited access to health care and research opportunities, as well as restrictions in their insurance coverage, with many relying on Medicare and Medicaid for health care coverage (Giuliano et al., 2000). Thus, present study findings might simply reflect the demographics of the clinic where it took place, which serves predominantly low-income, ethnic minorities within the VCC program. Such a sample increases homogeneity and restricts the range of core demographic variables. Study findings could also illustrate how individuals with private insurance are more likely to be employed, while those in VCC are more likely to be unemployed, affording them more time to participate in research. Lastly, the financial incentives for

study participants, while modest ($140 total), may also have contributed to the observed demographic pattern.

Mental Health-Related Conditions. The present study found consenters were more likely to endorse problems with anxiety, depression, migraines, and chronic pain than non-consenters. These findings are consistent with those reported for individuals enrolled in specialty-care substance abuse treatment programs. Specifically, the National Survey of Substance Abuse Treatment Services (NSSATS) found approximately 45% of Americans seeking substance use disorder treatment have been diagnosed with co-occurring mental and substance use disorders (SAMHSA, 2015). Literature has suggested that individuals with comorbidities may be more likely to seek treatment. This is due in part to the Berkson's bias, which states that persons with more than one disorder have an increased chance of being treated for either disorder, and in part to individuals being more likely to seek treatment due to the distressing symptoms of their comorbid mental health conditions (Hall & Farrell, 1997). Thus, individuals with comorbid conditions may also be more likely to consent to a clinical trial as a result of them being more aware that they are in need of help and motivated to seek services.

If present study findings are valid, and RCT enrollees present with more severe mental health problems than the broader population of primary care patients with problem substance use, results have important implications for treatment. Patients with co-occurring mental health and substance use disorders frequently have less motivation to change, are harder to engage, drop out of long-term programs more easily, and make slow progress (Horsfall et al., 2009). Further, these individuals often require additional help with housing and employment services during their treatment. An interdisciplinary

approach to care is recommended in order to address the unique challenges associated with treating substance use in the presence of other conditions (Kelly, Daley & Douaihy, 2012). With this pattern, a treatment may appear less effective when provided to a severe patient sample, when that same treatment might be effective and clinically useful for a less severe and more representative clinic sample. This is of particular concern with the SBIRT treatment model, which is focused on prevention and early intervention and may be less effective in persons with psychiatric comorbidities.

Sleep Behavior. Consistent with greater mental health comorbidity, consenters were more likely to report trouble falling asleep, poor sleep quality, and the use of sleep medications than non-consenters. The overlap between insomnia and substance use has been well established. Insomnia is not typically treated medically, and as a result, research has found that approximately 30% of insomniacs self-medicate with alcohol or over-the-counter (OTC) medications (Roehrs et al., 2002). While alcohol does initially promote sleep in low to moderate doses, its effects decrease with chronic use and it ultimately disrupts sleep-related physiology (Stein & Friedmann, 2006). Thus, research has also identified sleep disturbances as a consequence of alcohol use, with alcoholics experiencing prolonged sleep latency, decreased sleep time, decreased rapid eye movement sleep, decreased sleep efficiency, difficulty maintaining sleep, early awakening, and non-restorative sleep (Wallen et al., 2014). Consistent with psychiatric comorbidities, primary care patients have been found to be more likely to seek treatment for insomnia when in the presence of other medical conditions (Aikens & Rouse, 2005). Thus, individuals with sleep disturbances also may be more likely to consent to a clinical

trial as a result of them being better able to identify they are in need of services and motivated to seek treatment.

This overlap between sleep and substance use also has important implications for treatment. Sleep disturbances have been found to independently increase the risk for relapse to alcohol (Wallen et al., 2014). Due to similar neurobiological and psychosocial processes in sleep and addictive behaviors, recent research suggests that this pattern may be true for a range of psychoactive substances, including, cocaine, amphetamines, and nicotine, supporting sleep as a universal risk factor for relapse (Brower & Perron, 2010). Disturbed sleep patterns can persist for months to years following the initiation of abstinence. As a result, adjuvant sleep treatments may be necessary, including both CBT-I and pharmacologic approaches (Arnedt et al., 2007). Thus, treatments may not appear to be effective when tested without these additional components that address this heightened risk for relapse.

Substance Use. In order to qualify for the present study, participants had to screen positive for heavy/problem alcohol, illicit, and/or prescription drug misuse. Across these 3 domains, consenters were more likely to report recent illicit substance use than non-consenters. The National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), which surveyed a representative sample of the non-institutionalized population in the United States, found that individuals who are drug dependent are approximately four times more likely to receive help than those who are dependent only on alcohol (Grella et al., 2015). The illegal status of drugs may underlie this distinction, where misuse of alcohol is more socially normative and drug dependence is more easily identified as problematic.

In addition, consenters reported using illicit drugs more frequently than non-consenters, suggesting that the sample under investigation may also have a more severe substance use problem than the full population of interest. Similarly, consenters were more likely to report a family history of substance use than non-consenters. Research suggests that family history of substance use may be associated with an earlier age of onset, and in turn, greater severity of use (Johnson et al., 2000). This pattern may reflect that patients with more severe use may be better able to recognize that they are in need of treatment and therefore have more motivation to consent to an SBIRT trial. This pattern also has important implications for treatment. Although evidence for SBIRT is promising, there is less evidence in the literature for its efficacy among patients with very heavy use or dependence. A systematic review conducted by Saitz (2011) found that patients with heavy alcohol use or dependence were excluded from the majority of clinical trials. When they were included, the treatment approach showed no significant difference in alcohol severity. A similar review on the efficacy of SBIRT with drug use also demonstrated limited efficacy, suggesting that the treatment model also may not be effective when targeting other (non-alcohol) drugs of abuse (Saitz, 2014). Taken together, if individuals with more severe substance use are more likely to consent to participate, RCT outcomes may not generalize to less severe forms of use found among patients attending the clinic.

Multivariate Analysis. The multivariate regression analysis identified the variables included in a parsimonious model of predictors of research participation. Specifically, the final model found that older age, unemployment, illicit substance use, prescription misuse, family history of alcohol use, sleep disturbances, receiving health

professional recommendation to go on a diet, as well as more unstable living environments were all associated with research participation. Taken together, consenters reported experiencing a larger number of psychosocial and medical comorbidities than non-consenters. This pattern could be a result of these individuals being more likely to be in clinic for one of their concerns, providing easier access to screen them for eligibility and making the RCT visits more compatible with their schedule and time in the clinic. Further, these individuals may be able to more readily identify they are in need of services due to their comorbidities, as well as have more time to participate since they are unemployed. Lastly, this could be a result of non-consenters minimizing their problems and not providing an accurate reflection of their current health and functioning.

While the multivariate model provides a profile of individuals more likely to consent to research participation, it is important to note that this model only accounted for between 7.2% (Cox & Snell R Square) and 9.6% (Nagelkerke R Square) of the variance of subjects. While the clinical significance of these findings may appear limited, it is important to remember the present study was secondary analysis of existing data and survey items sampled broadly but with limited questions for each domain. Thus, present study results represent only the first step in a promising and important area of research with opportunities to further explore potential differences between those who do and do not consent to SBIRT research study participation.

Study Implications and Applications

The present study provides benchmark data on sample representativeness in a clinical trial of SBIRT. The anonymous computer-based primary care screening survey afforded a unique opportunity to compare RCT participants and non-participants across a

wider array of variables than previously found in the literature. Overall, consenters had a larger number and more severe problems across the domains surveyed. This could be a result of these individuals being able to more readily identify that they are in need of treatment with more motivation to participate in the trial. Conversely, it could also be a reflection of non-consenters minimizing their problems with less willingness to provide an accurate depiction of their current health and functioning.

Demographic factors, such as being unemployed and having no health insurance were also associated with research participation. This pattern may illustrate that unemployed patients consented to the research because they were not working and therefore had more time available for the study. Alternatively, the relationships might be more complex, with mental health issues and substance use contributing to job loss and unemployment.

While statistical differences were found between consenters and non-consenters, the final model accounted for only about 10% of the variance in research participation. However, the present study serves as the first step exploring potential differences between participants and non-participants, and given that the data across these broad domains accounted for variance in research participation, it affirms the need to explore these domains in greater detail in order to ensure the representativeness of SBIRT research. This is of particular importance given mixed results in SBIRT outcome studies targeting other drugs of abuse, with some showing positive findings (Madras et al., 2009), and other reporting no differences between SBIRT and control condition (Saitz, 2014). If clinical trials are conducted on more severe samples, the SBIRT intervention may be found to be ineffective, when in fact it could have great clinical utility for persons

with less severe use. Gaining a better understanding of the sample under investigation, and how their use compares to the population of interest, would ensure the findings are generalized appropriately.

In addition to the sample representativeness, it is also important to take note of the recruitment and consent process in the clinical trial. While many SBIRT studies do not report rates of informed consent, the present study rate (53%) was lower than others in the literature (e.g., Madras et al., 2009; Kaner et al., 2013), which could be a reflection of the overall study design. Participants completed the anonymous survey during their first appointment, and then if eligible, were asked to proceed to the baseline assessment. Thus, practical issues could have accounted for participants being unable or unwilling to make an additional time commitment beyond the initial screening phase. In addition, research has suggested that the method in which patients are recruited could influence the characteristics of the obtained sample, as well as treatment effects (Winhusen et al., 2012). For instance, consenters were more likely to be unemployed and uninsured, suggesting that the access to services and financial incentives may be more effective with this patient population. Further, more severe medical histories of consenters may have prompted them to seek services of any kind with greater motivation to enroll in the trial. Lastly, the stigma around substance use, particularly alcohol versus illicit substances, may also have played a role in willingness to participate. Gaining a better understanding of these factors could help tailor recruitment efforts to the target population and improve the representativeness of the sample.

Lastly, the present study provides important information about the characteristics of the patient population presenting in primary care clinics. Given that substance use

services have historically been in specialized treatment centers, the present study provides a better understanding of the demographics, medical backgrounds, psychosocial characteristics, and substance use behaviors of the 85% of patients who traditionally may never present for substance abuse treatment services. These findings can serve to inform the implementation and tailoring of SBIRT to meet patient needs in various medical care settings.

Study Strengths, Limitations, and Future Directions

Strengths

The present study had a number of important strengths. First, whenever possible, Health Cheq used reliable and valid measures to assess for problems in each domain of interest. Further, the format and delivery of the Health Cheq survey promoted patient anonymity and comfort. Patients were told that the survey was a "Patient Health Check-Up" with no mention of substance use, which may have increased patient willingness to complete the survey. When a survey is presented as a measure of substance use, it can influence the patient's decision to complete the survey, as well as their subsequent responses. The survey included many items that had nothing to do with substance use in an effort to mask the true purpose of the screener. Peedy, the computer avatar, asked questions regarding other health behaviors such as exercise, eating habits, and sleep to reduce the stigma associated with the screener and allow patients to get comfortable using the computer before answering questions regarding their substance use. In addition, the participant was informed that all of their responses would remain anonymous, which also served to promote patient comfort and limit fear of disclosing information on sensitive topics.

Second, while RCT eligibility had few exclusion criteria, promoting heterogeneity and sample representativeness, it also added to those who would be clinically eligible for and might benefit from SBIRT services. The limited exclusion criteria also made patients with comorbidities, polysubstance use, and different ethnic backgrounds eligible for the study, providing information across the spectrum of use and severity. This enabled the data to reflect the complexities that are typically seen in primary care.

Third, using Health Cheq as the initial screening tool offered a unique opportunity to collect data on this large pool of participants who often may not come to the attention of the research team. Clinical trials rarely have any information on patients who decline research participation beyond basic demographics. Health Cheq provided a rich dataset on the eligible pool of patients in order to examine any potential differences between consenters and non-consenters.

Fourth, the use of the electronic screener provided a more comprehensive, reliable, and less biased approach to collecting data than interviews and ratings conducted in clinical practice (Trull, 2007). Technology also offers increased privacy for participants, which may improve accuracy of responses when reporting on stigmatized health behaviors. In addition, Health Cheq used an animated avatar to ask questions and guide participants through the survey. The narrator is able to speak, move, and provide empathetic reflections (Pollick et al., 2015). This format is more engaging and less intimidating than traditional health screeners. Lastly, Health Cheq included branching logic that streamlined the screening tool and all answers were recorded by simply tapping responses from a list. This helped cut down on the overall time to complete the screener and limited missing data.

Limitations

Despite these strengths, some limitations were also present. First, the Health Cheq survey relied on retrospective, self-report information. Although self-reports are used extensively throughout clinical research, they are subject to biases that are difficult to control even under the best of circumstances. This is particularly true when respondents are asked to report on stigmatized behaviors such as substance use and HIV risk behaviors (Harrison, 1995; Smith et al., 2008). With Health Cheq, while the primary purpose of the survey was to identify those at risk for heavy/problem substance use, this was not made explicit during Health Cheq recruitment. Instead, it was described as an anonymous general health and risk behaviors survey. This was done in part, to minimize social desirability. Therefore the survey included questions that did not pertain to substance use. Research efforts to mask the primary purpose of the screener, however, may have become less successful over time, as the clinic became aware of an ongoing RCT that involved substance use. Patients could converse in the waiting area and this may have influenced how they responded to the substance-related survey items. However, the fact that the survey was anonymous may have mitigated these factors and promoted patient comfort in answering items honestly.

Second, the sample was recruited from an urban clinic that serves predominately low-income, ethnic minorities. The homogeneity of patients served in this setting limited the range for several demographic variables and may explain why study findings did not resemble those previously reported for patient demographics. A more heterogeneous sample may have revealed more information about the characteristics associated with research participation and improved the generalizability of study findings.

Third, the univariate analyses required a number of comparisons across groups, which increased the probability of a committing a Type I error. The larger the number of tests, the easier it is to detect an effect when in fact there is none (Abdi, 2007). However, the exploratory nature of the study necessitated a large number of comparisons in order to fully explore what domains may be of interest.

Lastly, the study did not specify whether marijuana use was for medicinal purposes, and instead classified other drugs as recreational/illicit or prescription, with marijuana categorized under recreational/illicit. Therefore, this could have resulted in a mischaracterization of reported substance use and skewed the obtained results. Further, the limited exclusion criteria enabled polysubstance use to be included in the study, with drug CAGE questions asked broadly across all substances (excluding alcohol), which often made it difficult to parse out the type of use and associated psychosocial and medical issues.

Future Directions

This present study serves as an initial investigation into characteristics associated with participation in a clinical trial of SBIRT. Using secondary data analyses, the study was limited by variables in the Health Cheq survey. Thus, future research should build upon these findings and include more detailed screeners of potential participants. Gaining a better understanding of the eligible pool of participants will ensure the obtained sample is representative and the findings are generalizable to the population of interest.

Efforts should also be made to follow patients throughout clinical trials to see how differences in participant characteristics may influence RCT outcomes. For instance, gaining a better understanding of how differences in substance use severity, family

history, risk behaviors, etc. are manifested in treatment outcomes provides information on how these differences are influencing clinical research and generalizability of study findings. Gaining a better understanding of these underlying factors would offer opportunities to tailor interventions to the specific needs of different patient populations.

Future research should also broaden this work to clinics that serve a broader spectrum of patients in order to see how these findings may vary with different socioeconomic and cultural backgrounds. This may need to be accomplished through multisite trials in order to obtain the full continuum of patients presenting in primary care. This research would provide important information on primary care patients as a whole and provide insight into how findings may vary across patient populations and clinical settings.

Lastly, future research should incorporate a measure of motivation when screening participants for eligibility in order to see how motivation may influence their willingness to participate. Further, efforts should be made to understand how motivation may influence treatment outcomes. This would provide valuable information on how motivation may correlate with specific conditions, as well as how this in turn may influence study participation and findings.

Conclusion

In summary, the present study offered a unique opportunity to compare RCT consenters and non-consenters across a wider array of variables than previously found in the literature. Overall, consenters reported a larger number and more severe problems across the many domains surveyed. These findings could have important implications for treatment outcomes, as well as the generalizability of study findings. The present study

serves as a preliminary analysis of predictors of research participation, and highlights the need to explore these factors in future research in order to ensure the representativeness of SBIRT research.

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