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Pragmatic trial of a Study Navigator Model (NAU) vs. Ambassador Model (N+) to increase enrollment to health research among community members who use illicit drugs

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Abstract

BACKGROUND—Although drug use is common in the population, drug users are sometimes excluded from research without justification. Two models of individualized study matching were compared for effectiveness in enrolling people who “endorsed current drug use” and those who “did not” into appropriate research.

METHODS—Participants in the NIDA-funded Transformative Approach to Reduce Research Disparities Towards Drug Users study (Navigation Study) were recruited through a Clinical and Translational Science Award (CTSA) community engagement model. Of the 614 community-recruited adults, 326 endorsed current drug use (cases); 288 did not (controls). Participants were randomized to one of two intervention groups: Navigation as Usual (NAU) [individualized study matching through a Study Navigator] or Enhanced Navigation (N+) [individualized study matching plus transportation and other assistance through an Ambassador]. Rates of enrollment into research studies were compared.

RESULTS—At 90 days, N+ vs. the NAU intervention was associated with higher enrollment among both drug users (36.0% N+ vs. 24.9% NAU) and non-drug users (45.5% N+ vs. 25.2% NAU). NAU attained the same rate of enrollment for users of drugs (24.9%) and non-users (25.2%); N+ had similar rates as well (36.0% drug users vs. 45.5% non-drug users). In addition,

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high rates of enrollment were achieved among all groups of participants, from 24.9% (drug users in NAU) to 45.5% (non-drug users in N+).

CONCLUSIONS—Both the NAU and N+ methods can reduce barriers and help users and non-users become part of the population that participates in research. Working with the local CTSA adds significant value to the research enterprise.

Keywords

drug use; RCT; CHWs; Ambassador; research participation; inclusive research; navigation

1. Introduction

Enrollment rates are less than optimal for all types of health research studies across the United States. Only two percent of the United States population participates in clinical trials each year (Getz et al., 2007). Lara and colleagues (2001) found that physicians recruiting at a cancer clinic enrolled only 14% of new patients into cancer clinical trials. According to the Agency for Healthcare Research and Quality (2012), three to twenty percent of those in eligible participant pools actually choose to participate in studies. Minority enrollment is especially low (Hawk et al., 2014). To reduce health disparities, recruited samples must include underrepresented populations.

Excluding traditionally underrepresented populations from health research, like persons who use illicit drugs, results in findings that are not generalizable. Nonetheless, drug users are frequently excluded from research—even research that specifically aims to test drug and alcohol treatment protocols (Blanco et al., 2008; Okuda et al., 2010).

Drug users are sometimes excluded from health research based on the misconception that they are not reliable or willing to participate in research (Striley, 2012). Some investigations indicate that underrepresented groups including drug users might not participate in research because they perceive research as inconvenient and burdensome, or they perceive researchers and/or the medical community as dishonest and uncaring (Barratt et al., 2007; Corbie-Smith et al., 1999; Giuliano et al., 2000; Ford et al., 2013). Other identified barriers to participation include skepticism of the informed consent process, inappropriately low incentives, and distrust of research that targets sub-populations (Fouad et al., 2000).

Barriers to the participation of “drug users” may be internally introduced through IRB members who perceive cash incentives (sometimes of any size) to be inappropriate and even unethical due to their belief that drug users will use the cash to buy drugs. Cottler et al. (1995) found from their studies of drug users in the community that cash was considered more valued, dignified, and less stigmatized than a certificate or coupon that required a form of ID for redemption. Deren et al. (1994) found that when cash remuneration was changed to a coupon requiring ID, participation in intervention sessions declined. Other findings indicate that neither the magnitude nor the mode of the incentives had a significant effect on rates of new drug use or perceptions of coercion (Festinger et al., 2005; Festinger and Dugosh, 2012).

Like any other potential research participants, drug users will enroll in research if efforts are made to reduce potential barriers. Recent research indicates that minority group members are overwhelmingly interested in and willing to participate in all types of health and medical research, though most have not been given the opportunity (Cottler et al., 2013; Hartz et al., 2011). In another report from this team, marijuana users were found to be as willing to participate in health research as non-users (Webb et al., 2015). Culturally sensitive advocates, trained to help potential research participants overcome barriers to participation, are considered to be the most important factor in the enrollment and retention process (Simmons et al., 2008; Striley et al., 2008).

In 2009, the National Institute on Drug Abuse (NIDA) requested scientific proposals to develop innovative and transformative research in tandem with the NIH Clinical and Translational Science Awards (CTSA). The purpose of the NIDA grant was to establish partnerships with the CTSA that could build upon the resources available at the CTSA sites. Given our strong linkage with our CTSA, we competed successfully for this award and developed an extension to our community engagement program, first at Washington University and subsequently at the University of Florida (UF). We tested the effectiveness of a Navigation as Usual (NAU) intervention versus an Enhanced Navigation (N+) intervention to increase research enrollment. We hypothesized that those assigned to an N+ intervention, which included an Ambassador (a person who helped navigate potential participants through each research milestone), would have a higher rate of enrollment in studies than those in the NAU intervention group, which received fewer hours of personalized attention, whether drug users or not. We also collaborated with the CTSA to provide a strong foundation for our work.

2. Material and Methods

The community engaged outreach model, HealthStreet, was founded by Dr. Linda Cottler in 1989 at Washington University in St. Louis, scaled up for the CTSA in 2007, and brought to UF in November 2011. HealthStreet was used to navigate participants into the NIDA-funded study, Transformative Approach to Reduce Research Disparities Towards Drug Users (also called the Navigation Study). HealthStreet is a community based effort funded in part by the UF Clinical and Translational Sciences Institute that works to reduce disparities in healthcare and research by linking people to medical and social services and opportunities to participate in research at UF. At any one time, HealthStreet recruits for about 100 clinical trials and observational studies for the majority of UF's 16 Colleges, involving over 130 different investigators who do research in many different areas of focus. A main goal of HealthStreet is to diversify research by including traditionally underrepresented groups. Community members are navigated to UF research studies based on their eligibility and interests.

Community Health Workers (CHWs) at HealthStreet are culturally sensitive and trusted members of the local community who are trained to help community members overcome potential barriers to enrolling in research and connect them with needed medical resources. CHWs meet community members in grocery stores, laundromats, beauty salons, health fairs, malls, parks, churches, and other places where people congregate. CHWs engage potential

participants by briefly describing the purpose of HealthStreet and then assessing their health needs and concerns.

Individuals interested in HealthStreet are led through an informed consent process that allows CHWs to interview them using a Health Intake Form, which assesses their demographic information, zip code of residence, primary health concerns, physical and psychiatric conditions, current medications, social determinants of health, and illicit drug use (lifetime and past 30 days).

UF IRB approved the HealthStreet and Navigation Study protocols. Certificates of Confidentiality for both studies were issued by NIDA. For the Navigation Study, individuals 18 to 80 years of age, living in Gainesville, and able to provide at least two contacts for a 30 and 60 day follow-up, were eligible. HealthStreet members who reported use of cocaine or crack, marijuana, heroin, speed or amphetamines, inhalants, or hallucinogens, or non-medical use of prescription stimulants, sedatives, or opioids in the past 12 months during the standard Health Intake were eligible for participation as cases for this study within a study. Eligible HealthStreet members who did not endorse past 12 month drug use were qualified for participation as controls. For those who were eligible and interested, the Project Coordinator explained the Navigation Study in detail and scheduled a baseline interview.

2.1. Baseline Protocol

The research assistants and Project Coordinator underwent three weeks of training on the protocol, proper administration of the assessments, and interviewer conduct before beginning baseline sessions. Ongoing quality control of the data was guaranteed by the auditory taping of all research interviews and the monitoring of randomly chosen interviews. This ensured accuracy and fidelity to the protocols.

After written consent for the Navigation Study was received, the interviewer administered:

The Substance Abuse Module 12 Month Version (SAM; Horton et al., 2000), to assess in more detail than was given in the HealthStreet intake on the use of nicotine, alcohol, marijuana, stimulants, sedatives, club drugs, cocaine, heroin, opioids, PCP, hallucinogens, inhalants, and other illicit drugs in the past 12 months. Physical, social, and psychological consequences of specific drug use, as defined by DSM-IV were also elicited.

After the 60-minute baseline assessments were completed the participant was randomized to a group assignment: Navigation as Usual (NAU) or Enhanced Navigation (N+).

Randomization codes were generated by our Research Statistician before recruitment using SAS 9.3 software and were provided to the participant in a sealed envelope to open in the presence of the Project Coordinator. Depending on the randomization code, the participant was then introduced to either the Ambassador (N+) or the Study Navigator (NAU). Participants randomized to NAU were reminded of the 30, 60 and 90 day follow-up interviews. Participants randomized to N+ were introduced to the Ambassador who reminded them of the follow-up interviews and of the additional help offered to them. Participants in both groups were remunerated 40 USD for their participation, 20 USD at

baseline and 20 USD at final follow-up. Both groups had already received a baseline HealthStreet effort consisting of referrals as described below under NAU.

2.2. Navigation as Usual vs. Enhanced Navigation

Navigation as Usual (NAU) consisted of utilizing the HealthStreet Study Navigator to determine if any UF study matched the participant's stated health concern or condition. The process of individualized study matching also required a thorough understanding of each study's purpose, inclusion and exclusion criteria, risks and benefits, and participation requirements; this information was then relayed to the potential participant. The Study Navigator contacted participants to discuss all aspects of the study and whether participants were interested in the study for which they qualified. If the participant was interested, the Study Navigator forwarded the name and contact information to the specific UF study coordinator, who then initiated contact. When the person did not qualify, or finished their participation, the Study Navigator would attempt to link them to another study. After ongoing follow-up, the Study Navigator recorded enrollments for eligible participants and reasons for exclusion for ineligible participants. Enrollment status of all Navigation Study participants was regularly collected from UF study coordinators. Participants also received referrals to medical and social services.

Enhanced Navigation (N+) consisted of the standard HealthStreet intervention of individualized study matching using an Ambassador instead of a Study Navigator. The Ambassador performed the roles of the NAU Study Navigator with the addition of being available to be engaged in all research milestones, including follow up calls that set up study appointments, placing reminder calls to the participant, and providing transportation as needed beyond the minimal HealthStreet (or NAU) effort.

Ambassadors possessed characteristics similar to those described by Cottler et al. in their earlier paper (1996), including doggedness, excellent interpersonal skills, commitment, and cultural competence. The Ambassador also helped participants understand consent forms and study details, and advocated for the person's enrollment, when appropriate. The Ambassador also provided referrals to needed medical and social services as CHWs did for the NAU assigned participants. One of the biggest differences between the Navigators and Ambassadors was that there was only one Ambassador to assist with needs, whereas, there were multiple Navigators. The personalized attention was the unique feature.

2.3. Follow-up Protocols

To evaluate the effectiveness of the intervention to enroll drug users into relevant studies, we recontacted them at 30, 60 and 90 days post-randomization. At the follow-ups we assessed medical and social services received, past 30 day substance use, satisfaction with the Navigation Study, and, if applicable, satisfaction with studies in which participants were enrolled. The 90 day follow-up interview repeated questions from baseline, including substance use.

3. Results

Although 619 people had been prescreened by HealthStreet staff before navigation to the Navigation Study Project Coordinator, two were excluded because they lived outside of Gainesville, and three declined to participate. Thus, 614 (99%) were randomized to NAU or N+. Patterns of completion are shown in Table 1. While 67.3% of the sample completed all three follow-ups, with only 8.1% completing none, all participants from the Navigation Study were analyzed with an intent-to-treat model.

Significant differences at baseline emerged between drug users and non-users with users significantly more likely than non-users to have lower self-perceived health and to be: younger, male, never married, of lower educational attainment, and uninsured (see Table 2).

Our primary outcome was to link community members to CTSA-member studies while achieving a high enrollment rate at 90 days, among both N+ and NAU group members, and among cases (drug users) and controls (non-users). Overall, over a 90 day period, we achieved a 32.7% enrollment rate among the entire sample: 40.5% among N+ versus 25.0% among NAU. As shown in Table 3, Enhanced Navigation (N+) resulted in a higher enrollment rate compared to Navigation as Usual (NAU) for both drug users (36.0% N+ vs. 24.9% NAU) and non-users (45.5% N+ vs. 25.2% NAU). In both randomization groups, drug users and non-users attained similar rates of enrollment (NAU drug users, 24.9% vs. non-drug users, 25.2% and N+ drug users, 36.0% vs. non-drug users, 45.5%). Of note are the high rates of enrollment in health research among all participants (from 24.9% to 45.5%).

4. Discussion

At the University of Florida, efforts are underway to bring underrepresented populations into health research, which will help the translation of clinical trials into real world application. Enrollment rates of 32.7% overall for community members to be enrolled in health research studies are higher than a study in one's own practice (Lara et al, 2001). These efforts may reflect the success of new models of community engagement, especially through the efforts of CTSA across the country. These results indicate that with the introduction of an Ambassador to guide people through research study milestones, drugs users and non-users alike can be recruited at high rates into health research. Drug users were enrolled in studies at the same rate as non-users regardless of their assignment. This is important to the field.

The person-centered approaches used in this study – whether the regular navigation process through HealthStreet (NAU) or the enhanced approach (N+) – have proven to be successful in enrolling people in research. Our strategy goes well beyond CHWs approaching community members and explaining available studies. The NAU and N+ approaches are based on respect for the person's autonomy and worth, a thorough understanding of the requirements of open research studies, an efficient process to ensure that study coordinators know of a person's interest, meaningful follow-up to determine results, and sincere interest in linking people and following up with them. In addition, the N+ added transportation and

the other individualized elements discussed. High rates of enrollment found in this study can be attributed to these person-centered efforts and approaches.

This study is the first of its kind to directly compare two person-centered approaches to increase enrollment to health research studies among drug users. It adds to our understanding of the feasibility of enrolling those who are often excluded as well as our methods of reducing barriers to enrollment.

Some limitations are to be noted. Because the study drew from a population in North Central Florida, findings may not be generalizable to other areas though elements of our model have been utilized in five other CTSI sites (Cottler et al., 2013). The geographic location may present different patterns of drug use among community members; our population, as noted in Table 2, enrolled predominantly current marijuana users.

Our findings highlight the importance of linking with the local CTSA, and of using person-centered, barrier reducing approaches to helping community members become a part of the population of people who participate in research. These methods are routinely used at HealthStreet and valued by the CTSA's across the United States. The enhanced model provides additional assistance for those with more difficult life circumstances. The findings suggest that treating people as people first and not disqualifying them from participation for non-medical reasons will increase the diversity of research participant populations. As noted earlier by members of this team (Webb et al., 2015), drug users are eager to participate in health research. Importantly, their participation meets the ethical requirement for justice demanded by the Belmont Report (The National Commission, 1979; Striley, 2011). Persons who use drugs should be offered the same opportunity to have their voice heard in the research enterprise as people who do not. This is especially important given the increasing national attention to and acceptability of both medical and recreational use of marijuana.

Future studies should replicate the findings among populations with more diverse drug use and future analyses should determine the specific elements of the choice to participate or not. Additionally, the intervention should be tested in metropolitan and rural areas, with their unique barriers to enrollment and diversity of substances available. Future studies should also assess both the feasibility of these interventions over a longer period of time and their effectiveness among other commonly excluded populations.

In the end, we succeeded in NIDA's goal to not only integrate with our local CTSA, but to take a leading role in the community engagement program. This effort gave more people a voice in research for the first time.

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Highlights

- The N+ group attained higher enrollment compared to the Navigation as Usual (NAU) group for both drug users and non-users.
- In both randomization groups, drug users and non-users attained similar rates of enrollment.
- Of note are the high rates of enrollment in research among all participants (from 24.9% to 45.5%).
- Both methods can help users and non-users participate in health research.

Table 1

Patterns of Follow-Up Completion

30-Day Follow-Up	60-Day Follow-Up	90-Day Follow-Up	N (%)
No	No	No	50 (8.1)
No	No	Yes	6 (1.0)
No	Yes	No	10 (1.6)
No	Yes	Yes	20 (3.3)
Yes	No	No	34 (5.5)
Yes	No	Yes	28 (4.6)
Yes	Yes	No	53 (8.6)
Yes	Yes	Yes	413 (67.3)

Table 2

Baseline Demographic Characteristics of Study Sample (N = 614) by Drug Use Status

	Non-Drug User (N = 288)	Drug User (N = 326)	Chisq or T-Test
	N (%) / Mean (Std) (Range)	N (%) / Mean (Std) (Range)	p
Age	45.56 (13.51) (18 – 78)	41.55 (13.32) (18 – 75)	0.0002
Gender			0.0002
Male	114 (39.58)	178 (54.60)	
Female	174 (60.42)	148 (45.40)	
Race/Ethnicity			0.6486
Black	152 (52.78)	178 (54.60)	
White, Non-Hispanic	102 (35.42)	117 (35.89)	
Other	34 (11.81)	31 (9.51)	
Marital Status			0.0005
Married	56 (19.44)	33 (10.12)	
Widowed/Separated/Divorced	110 (38.19)	112 (34.36)	
Never Married	122 (42.36)	181 (55.52)	
Education			<0.0001
Less than High School	42 (14.58)	71 (21.78)	
High School Diploma or GED	162 (56.25)	206 (63.19)	
College Degree	63 (21.88)	44 (13.50)	
Graduate Degree	21 (7.29)	5 (1.53)	
Years of School Completed	13.34 (2.97) (4 – 26)	12.36 (2.32) (5 – 21)	<0.0001
Self-Perceived Health			0.0237
Excellent or Good	165 (57.29)	157 (48.16)	
Fair or Poor	123 (42.71)	169 (51.84)	
Any Health Insurance	169 (58.68)	151 (46.32)	0.0022
Any Employment	136 (47.22)	168 (51.53)	0.2867
Illicit Drug Use Past 12 Months			
Marijuana	N/A	295 (90.49)	N/A
Stimulants (Methamphetamine, etc.)	N/A	6 (1.84)	N/A
Club Drugs	1 (0.35)	24 (7.36)	0.0005
Cocaine or Crack	N/A	63 (19.33)	N/A
Heroin or Opium	N/A	5 (1.53)	N/A
PCP	N/A	0 (0.00)	N/A
Hallucinogens	N/A	17 (5.21)	N/A
Inhalants	N/A	1 (0.31)	N/A
Other Illegal Drugs	N/A	4 (1.23)	N/A
Non-Medical Use of Prescription Drugs (Stimulants, Sedatives, or Opioids)	N/A	71 (21.78)	N/A

Table 3

Study Enrollment Rates at 90 Days by Drug Use and Intervention Status *

	Non-Drug User (N=288)		Drug User (N=326)		p-value				Total (N=614)
	NAU (N=143) (A)	N+ (N=145) (B)	NAU (N=165) (C)	N+ (N=161) (D)	A vs. B	C vs. D	A vs. C	B vs. D	
Participants Enrolled (%)	36 (25.2)	66 (45.5)	41 (24.9)	58 (36.0)	0.0003	0.0282	0.9474	0.0918	201 (32.7)

* Intent-to-treat analysis