

Treatment Research Institute

Annual Progress Report: 2010 Nonformula Grant

Reporting Period

July 1, 2013 – June 30, 2014

Nonformula Grant Overview

Treatment Research Institute received \$4,493,185 in nonformula funds for the grant award period June 1, 2011 through May 31, 2015. Accomplishments for the reporting period are described below.

Research Project: Project Title and Purpose

Integrating Substance Abuse Assessment and Intervention in Primary Care Settings - The purpose of the proposed studies are to compare screening, brief intervention, and referral to treatment (SBIRT) to a screening protocol which features an expanded intervention (SBIRT+) for addressing substance use in primary care settings in underserved urban neighborhoods. We will implement SBIRT in three primary care centers, and conduct a randomized controlled trial comparing treatment engagement, substance use, and cost-effectiveness outcomes between SBIRT and SBIRT+ for 600 randomly assigned patients who will be followed over 12 months. The proposal features implementation and sustainability evaluations. Completion of this project will enable our team to conclude whether expanded brief intervention is more effective than a standard SBIRT protocol, and whether this expanded intervention is sustainable and cost-effective.

Anticipated Duration of Project

6/1/2011 - 5/31/2015

Project Overview

The broad research objectives of this project are to assess the effectiveness and sustainability of a model of behavioral health integration directly into primary care. This model targets screening, expanded brief intervention, and ongoing monitoring of substance users, and will address significant gaps in scientific understanding of the broad effectiveness of brief intervention for substance use in primary care settings.

Specific Aim 1 - To implement a high fidelity SBIRT protocol with computerized screening technology into three primary care clinics in urban Philadelphia, and to train three behavioral health counselors in an expanded brief intervention protocol (SBIRT+); *Specific Aim 2* - To conduct a randomized controlled trial to assess whether patients assigned to receive SBIRT+ will attend more substance intervention and treatment sessions, demonstrate greater reductions in

drug use, and demonstrate improved medical, employment, legal, and psychiatric function as well as reduced HIV risk behaviors than patients assigned to SBIRT. This trial will also address whether the introduction of SBIRT and SBIRT+ in primary care clinics is cost-effective relative to societal costs; *Specific Aim 3* - To determine whether SBIRT and SBIRT+ are sustainable in primary care clinics as research funding for behavioral health counselors is phased out in Year 4 of the project; *Specific Aim 4* - To conduct a process evaluation of SBIRT+ at the three collaborating clinics consisting of focus groups and structured interviews to assess implementation barriers and workforce attitudinal shifts to help inform methods to further disseminate SBIRT or SBIRT+, should the trial prove it is sustainable and cost-effective; *Specific Aim 5* - To provide a clinical research training environment for graduate and undergraduate students from Lincoln University; this training experience will balance hands-on clinical data collection and didactic training.

After implementing SBIRT as standard practice in three multi-provider primary care clinics which operate in underserved neighborhoods in Philadelphia and training behavioral health consultants in the provision of an expanded version of SBIRT that incorporates ongoing monitoring, we will randomly assign 600 patients to receive: 1) one session of brief intervention (SBIRT) or 2) 2-6 sessions of brief intervention with ongoing telephone monitoring (SBIRT+). Patients will be followed-up every 3 months for 12 months with a multi-dimensional assessment and biological verification of drug use. We will conduct an implementation process evaluation, a sustainability evaluation at study end, and a cost-effectiveness evaluation of the two interventions.

Principal Investigator

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Other Participating Researchers

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Caryn Gratz, MSS, Elizabeth A. Byrne, MA, Jennifer Lauby, PhD, Mary Milnamow, BA, Lisa Bond, PhD - employed by Public Health Management Corporation
Patricia Gerrity, PhD, RN – employed by 11th Street Family Health Services of Drexel University
Donna L. Torrissi, CRNP, Virginia A. Davidov, LCSW – employed by Resources for Human Development, Inc., Family Practice and Counseling Network
Judith A. W. Thomas, EdD – employed by Lincoln University
Daniel Polsky, PhD – employed by University of Pennsylvania School of Medicine
Holly Hagle, MA, PhD candidate – employed by Institute for Research, Education, and Training in Addictions

Expected Research Outcomes and Benefits

Health Benefit Gains: Individuals who abuse illicit substances comprise a vulnerable population, as they are at greater risk of contracting HIV, experiencing chronic medical conditions and early mortality. The participants in this research, and by extension, the non-participants at the collaborating clinics in which this project is hosted, will be exposed to an intervention which should reduce illicit substance use, promote greater treatment engagement in specialty care, and improve their general medical outcomes.

Scientific Knowledge Gains: This project will address a gap in the scientific literature regarding a model of behavioral health integration that has been shown to effectively address alcohol abuse, but has not been rigorously studied in the case of illicit drug use. The research project is powered to detect potential differential effects of two interventions on harder illicit drug users (such as heroin and cocaine users) compared to primary marijuana users and primary alcohol users. The research project will improve implementation knowledge, and will include a robust assessment of the intervention's cost-effectiveness and sustainability.

Collaborative Gains: This project will provide a vehicle to foster a growing collaborative relationship between scientists at the Treatment Research Institute (TRI) and the University of Pennsylvania with scientist-practitioners from the Public Health Management Corporation, Drexel University Health Services, and the Family Practice and Counseling Network in Federally Qualified Healthcare Center settings. These relationships will provide bi-directional knowledge transfer, as scientists from TRI will be able to share broad behavioral health treatment knowledge with the primary care providers, and the providers will be able to shape future research efforts; we envision future and ongoing collaborative projects and grant applications.

Educational Gains: Students from Lincoln University will experience a broad and enriching internship in health systems and clinical research that will lead many of them to pursue careers in health research.

Summary of Research Completed

During the current reporting period we completed several goals of Phase 2. These activities involved the following Specific Aims: 2) conduct a randomized controlled trial to assess whether patients assigned to receive SBIRT+ will attend more substance intervention and treatment sessions, demonstrate greater improvements in drug use, and demonstrate improved medical, employment, legal, and psychiatric function as well as reduced HIV risk behaviors than patients assigned to SBIRT, 3) determine whether SBIRT and SBIRT+ are sustainable in primary care clinics, 4) conduct a process evaluation of SBIRT and SBIRT+, and 5) provide clinical research training for undergraduate students from Lincoln University. We present our work as it relates to relevant Specific Aims.

Specific Aim 2: Our goals for this reporting period were to: recruit and randomize 348 participants for the Randomized Controlled Trial and complete study enrollment; initiate intervention fidelity rating; initiate cost-effectiveness data collection; and give a presentation at a

national meeting.

On June 13th, 2014 we completed study enrollment. In the past year, we enrolled 348 study participants and reached our goal of 600 participants enrolled. Overall, the participating health centers screened 10,935 patients for substance use. Of those, 4,232 were identified as potentially using substances at risky levels, and 2,011 were further screened for study eligibility. Of those screened for the study, 871 met criteria, and 301 were enrolled and randomized to receive SBIRT, while 299 were randomized to receive SBIRT+. See Table 1 for final screening and enrollment rates by site. While we originally planned to enroll 200 participants at each site, Site 1 was only able to enroll 117 participants. We feel that this was due to 1) a lack of buy-in from personnel tasked with conducting the initial screeners and responsible for making referrals to the study, 2) a lower than expected eligibility rate, and 3) a large number of patients that were either not interested or not able to participate. Fortunately, we were able to recruit more than 200 from each of the other two sites, and were thus able to reach our overall recruitment goal.

In this third project year, we continued our ongoing data collection, cleaning, and monitoring for the randomized controlled trial. Data collection follow-up rates are presented in Table 2. While our focus of the past year was completing participant enrollment, we have also been monitoring our follow-up rates. We employed several tactics to increase our follow-up rates, including adding research staff to contact participants and schedule interviews, mailing reminder letters to participants, and obtaining up to date contact information. We have begun focused efforts to reduce the poor follow up rates at Site 3 by providing extra staff support and extending the assessment completion windows for participants. We feel that with these efforts, we can significantly increase our rates.

We also began collecting data for our cost effectiveness analyses. We met with our economic consultant to this project, Daniel Polsky, PhD, in order to review our original goals, hypotheses, and proposed methods. We then tailored our data collection instruments to these goals and hypotheses. We originally planned to use the Drug Abuse Treatment Cost Analysis Program (DATCAP) to assess cost-effectiveness. The Program-based DATCAP and Patient-based DATCAP are reliable instruments widely used by substance abuse treatment programs for the collection and organization of programmatic costs and participant-based costs, respectively. However, upon further review and based on our experiences over the past 2 years working in the Federally Qualified Health Centers (FQHCs), we determined that the forms would need major modifications in order to be relevant in these settings. Additionally, many of the topics covered in this instrument were not necessary for our analysis comparing the two treatment conditions. We therefore developed new items for our economic analyses. We added several questions to our patient measures to assess the financial cost of the interventions to patients, and began collecting this information as a part of the 3-month follow-up interview. In order to determine the cost of implementing SBIRT+ compared to SBIRT, we developed a form to collect information on the time it takes to complete SBIRT and SBIRT+ intervention activities. This form is administered to Medical Assistants, Providers, and Behavioral Health Consultants (BHCs), and we began collecting it at the end of this project year.

During this reporting period we continued monitoring for intervention fidelity by tracking SBIRT+ session completion rates as well as through clinical supervision. The study clinical

supervisor regularly listens to audio-recorded sessions as a part of her supervision, and discusses any instances of deviation during her bi-weekly supervision meetings with the BHCs. The clinical supervisor also reviews intervention checklists that the BHCs complete for each session. While several clients are still in active treatment and are receiving intervention sessions, preliminary SBIRT+ session completion rates are presented in Table 3.

Finally, we presented at 3 national conferences in the past year. First, Dr. Brooks presented at the Clinical Trials Network “Preparing for Change: Emerging Models for Integrated Healthcare Delivery Conference” on March 21st, 2014 about our experiences to date with implementing screening and brief intervention for substance use into primary care settings. We discussed many of the barriers identified throughout the Formative and Process Evaluation, and the various ways that we addressed these barriers (as reported in our annual report for 2013). Dr. Brooks also presented results on feasibility and acceptability of screening and brief treatment for illicit drug use in primary care at the 76th Annual Meeting of the College on Problems of Drug Dependence on June 16th, 2014 in San Juan, Puerto Rico. We presented preliminary participant characteristics (Table 4), rates of session attendance (rates presented were similar to those presented here in Table 2), and preliminary results of patient satisfaction. Patients felt that it was extremely helpful to be asked about their drug and alcohol use at the health center, and were very comfortable discussing their drug and alcohol use. Overall, these results showed that screening and onsite brief intervention / brief treatment is feasible in urban FQHCS, and heavy substance users find returning for multiple brief treatment sessions acceptable. Finally, Dr. Brooks, Elizabeth Byrne, and Kimberly Malayter, one of the project BHCs, presented at the 2014 Health Center and Public Housing National Symposium on June 10th, 2014, in Alexandria, Virginia. In a workshop format, we presented on the study design and procedures, the intervention protocol, and results on feasibility and acceptability. We also presented 2 case studies to demonstrate the utility of SBIRT in primary care settings.

Specific Aim 3: Our goals for this specific aim, to conduct a sustainability evaluation, were originally to be completed in our final project year. However, as recruitment began winding down at the end of this project year, we began discussing the sustainability of screening and brief interventions for substance use within the primary care centers. At the final two Steering Committee meetings of this project year, we started discussions with site representatives about ways to continue screening for substance use once recruitment is over. We have also starting discussions on billing for SBIRT and SBIRT+ services so that sustained efforts would be economically feasible.

Specific Aim 4: Our goals for this reporting period were to: complete evaluation of training activities; complete Time 2 Patient and Provider interviews including transcription and report compilation; and initiate Time 3 Patient and Provider Interviews.

In this project year we completed all of the scheduled Time 2 Provider Interviews, transcriptions, and summary reports. Methods and preliminary results from these interviews were reported at our previous annual report. The final results from these interviews are presented in Table 5, and described briefly here. In general, clinic staff were very supportive of the project and were able to articulate how the project has benefited their clinics and patients. They were also supportive of sustaining the screening and SBIRT intervention after the end of the research project, although

there was concern about whether staff would have the resources to continue to provide the service. Most staff felt that providers' brief time with patients already includes extensive issues to address, which limits their ability to provide any substance use intervention. BHCs were seen as being better equipped to address the complex mental health needs of patients with substance use problems.

We initiated Time 2 Patient interviews at the end of this project year. This was later than we originally planned in order to sample from those patients who were enrolled mid-way through recruitment when health center screening procedures were more firmly in place. In this past year, we also decided to delay the Time 3 Patient and Provider Interviews, along with the evaluation of training activities, so that they could take place a few months following the close of recruitment.

Specific Aim 5: Our goals for this reporting period were to: complete 2 student internships including presentations of students' projects; and initiate 2 new student internships, including developing projects and completing Human Subjects trainings.

We completed our goals for this project year. Two students completed their internship last summer. We presented on their experiences during the first 6 weeks of the 12-week internship in last year's annual report. In the remaining 6 weeks, the interns were able to visit the research sites and observe screenings, as well as participant recruitment and enrollment. They also each completed a project using data collected from provider surveys, key informant interviews, as well as patient satisfaction surveys.

Our final 2 students began their 12-week internship at the end of this project year. They have completed mandatory trainings on Human Subjects Projects, HIPAA, participant confidentiality, data integrity, informed consent, and administering assessments. They visited each site to observe data collection several times, and completed several readings on SBIRT, Motivational Interviewing, and research methods. They have also attended presentations of scientific research at TRI, and met with Investigators multiple times to discuss SBIRT, substance use, and career goals. Finally, they have begun developing ideas for their research projects.

Table 1. Enrollment

	Site 1	Site 2	Site 3	Total
Number Screened	5459	1847	3629	10935
Number Identified for Substance Abuse	1431	1555	1246	4232
Number Screened for Eligibility Criteria	853	494	664	2011
Number Meeting Eligibility Criteria	214	280	377	871
Number Enrolled and Randomized	117	235	248	600
SBIRT	60	118	123	301
SBIRT+	57	117	125	299

Table 2. Follow-up Rates.

	Site 1		Site 2		Site 3	
	SBIRT	SBIRT+	SBIRT	SBIRT+	SBIRT	SBIRT+
3-Month	73%	63%	76%	79%	69%	66%
6-Month	71%	64%	75%	77%	56%	55%
9-Month	76%	60%	70%	78%	48%	63%
12-Month	79%	70%	73%	72%	42%	52%

Table 3. Treatment Fidelity

	SBIRT	SBIRT+
Participants Enrolled	301	299
Session Attendance N (%)		
Session 1	295 (98%)	295 (99%)
Session 2	1 (0.3%)	234 (78%)
Session 3	0	165 (55%)
Session 4	0	114 (38%)
Session 5	0	77 (26%)
Session 6	0	51 (17%)

Table 4. Preliminary Participant Baseline Substance Use Characteristics.

	SBIRT	SBIRT+	p-value
Primary Substance			.814
Alcohol	33.0%	35.5%	
Marijuana	37.9%	37.1%	
Other Illicit Substances	29.1%	27.4%	
Mean Days of Any Alcohol Use (SD)	9.51 (9.77)	10.44 (10.07)	.283
Mean Days of Heavy Alcohol Use (SD)	5.39 (8.29)	5.33 (8.44)	.939
Mean Days Marijuana Use (SD)	11.29 (12.61)	11.45 (12.75)	.885
Mean Days Any Illicit Drug Use (SD)	14.44 (12.3)	13.81 (12.29)	.559
Mean Days Used Primary Substance (SD)	16.71 (11.12)	15.94 (11.48)	.441
Previously In Treatment	49.2%	50.4%	.791

Table 5. Findings from Key Informant Interviews

Successes
Staff perceived the project as helping patients
Identified D&A issues earlier, especially for people who might have gone unnoticed
Built trust among clinic population to integrate D&A care; available to patient when ready to address substance use problems.
Proactively addressed D&A issues for better patient health and well-being outcomes
Increased and improved clinic services
Challenges
Inconsistency in screening procedures
Lack of time to address patients' needs
Limited space to work with patients/participants
Lack of communication with TRI researchers
Lack of understanding of study procedures and protocols
Lack information about SBIRT & SBIRT+ , including impact on patients
Recommendations
Provide clarity on roles & responsibilities of staff in early stages of project implementation
Attend team meetings to discuss progress and share information; staff believed if they were better informed that they could alleviate patients concerns and worries
Discuss more personal patient stories with staff to increase buy-in
Share preliminary findings
Provide positive reinforcement for reaching enrollment goals