Mediation Analysis of the Efficacy of a Training and Technical Assistance Implementation Strategy on Intention to Implement a Couple-based HIV/STI Prevention Intervention

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ABSTRACT

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The purpose of this study was to examine the effectiveness and exposure of an implementation strategy, which included a 4-day in-class training with two follow-up technical assistance calls, on mediating factors hypothesized to be positively associated with staff's intention to use a five-session, couples-based HIV and other sexually transmitted prevention intervention.

The Consolidated Framework for Implementation Research (CFIR) guided the study aims and analysis of the direct effect of exposure to the implementation strategy and 3 factors hypothesized to mediate the implementation strategies' effect on intention to implement a couples-based intervention. Individual staff characteristics and an organizational process variable informed by Social Cognitive Theory (SCT), the Diffusion of Innovation Theory and Theory of Planned Action were examined. Two hundred and fifty-three staff, predominantly African American and Latina, from 80 organizations, were recruited from HIV service agencies, clinics and community-based organization from New York City and other regions of New York State. They were randomized by agency to either a multimedia condition or a traditional paper-based version of the couples-based intervention and received the implementation strategy 4-day, in-class intervention training followed by a technical assistance phone call at 3 and 6-months post training. Findings suggest that greater exposure to the implementation strategy in days and contacts was significantly associated with an increase in staff's intention to implement the intervention at six months. Further, while a statistically significant effect of the implementation strategy dose on the mediators examined was not detected, the implementer's experience of these mediators defined as self-efficacy for couples-based implementation, positive perception of the intervention's characteristics and

the perceived availability of an organizational intervention Champion was found to be significantly associated with the outcome variable intention to implement, and also was found to reduce the dosage effect of the implementation strategy on intention. Further examination of the implementation strategy's content and dosage is needed to identify how increased intention to utilize an intervention at 6 months and 12 months following training and technical assistance may be enhanced through greater attention to and measurement of these mediators in addition to the implementation strategy dosage effect. Of note, the dosage effect on intention was found to diminish at the 12 month follow-up period suggesting the importance of timely support and planning prior to and post implementation strategies to increase utilization of an innovation. Implications for HIV prevention theory, and social work research, practice and policy are discussed.

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.....T. H.

DEDICATION

I dedicate this work to my life partner, Joseph Anthony Cuen, who I tragically lost during the course of this program. With his encouragement I launched into this degree program and remained emboldened by the memories we shared of so many of our friends and colleagues who died from HIV/AIDS-related causes. Further, I dedicate the work to the many service providers, researchers, and advocates that work tirelessly to mitigate and defeat HIV and the impact of addiction in our communities.

Chapter I:

INTRODUCTION

Scope of the problem

While there have been some successes, innovative and cost effective behavior change strategies are still required to slow the spread of HIV and AIDS and to help those already infected to maintain their health (ONAP, 2015). For over 30 years social scientists and public health researchers have developed and tested interventions to address high-risk behaviors to reduce HIV and other sexually transmitted infections (STIs) (Dean, Hall, & Martin, 1988). Many studies have shown the effectiveness of community-, small group- and individual-level interventions while only Connect and an adaptation called SMART couples for HIV treatment adherence have utilized a couples-based behavioral approach for HIV prevention in the United States (Card, Benner, Shields, & Feinstein, 2001; El-Bassel et al., 2003; Fixsen, Naoom, Blase, & Friedman, 2005; Kelly, 2002; Kelly et al., 2000a). Couples-based HIV/STI prevention interventions have shown to be efficacious in reducing transmission by enhancing condom use, reducing sexual and drug sharing risks (El-Bassel, Gilbert, et al., 2010; El-Bassel et al., 2001; El-Bassel et al., 2003; El-Bassel et al., 2005; Purcell et al., 2014; Remien et al., 2005). Additionally, a dyadic-based intervention has demonstrated effectiveness in increasing adherence to HIV treatment regimens with HIV serodiscordant couples (Anti-retroviral adherence) (Hunt, 2013; Remien et al., 2005; Rodger, Cambiano, Bruun, & et al., 2016), and post-exposure prophylaxis (PrEP) to protect the partner without ending the relationship (Ware et al., 2012). Relationship quality has been identified as a significant correlate of adherence self-efficacy and suggests that greater relationship autonomy and intimacy may support confidence in one's ability to adhere to treatment. The partner's positive belief in the treatment outcomes is positively associated with the primary patient's adherence (Johnson et al., 2012). HIV testing with Couples-based HIV testing and counseling (CHTC) has shown effectiveness (Allen, 2002; Becker, Mlay, Schwandt, & Lyamuya, 2010; Neme, Goldenberg, Stekler, Sullivan, & Stephenson, 2015; Stephenson et

al., 2011) as decisions are made together as a couple. In spite of evidence of effectiveness, few organizations have adopted couples-based programming as evidenced by the few agencies funded by the CDC and state health departments to implement a couples-based prevention intervention (CDC, 2015; DANYA, 2015; Witte et al., 2014) . Examination of implementation strategies including training and technical assistance may serve to enhance facilitating factors associated with implementation such as implementer self-efficacy (Aarons, Hurlburt, & Horwitz, 2011; Bandura, 1986; Saks, 1995), positive perception of the intervention (Dearing, 2009; Greenhalgh, Glenn, Macfarlane, Bate, & Kyriakidou, 2004; Rogers, Medina, Rivera, & Wiley, 2005) and availability of organizational support (Aarons, Horowitz, Dlugosz, & Ehrhart, 2012; Glisson et al., 2008; Owczarzak & Dickson-Gomez, 2011; Packard & Shih, 2014) that are known to promote intention (Ajzen, 1991; Fishbein, 1975; Gollwitzer & Brandstätter, 1997; Webb & Sheeran, 2008) and ultimately utilization of this proven method for HIV/STI prevention.

Implementation science

Implementation is defined as a process of utilizing or integrating evidence-based interventions in practice, and implementation strategy as a planned process, activities and resources used to support utilization of an intervention in a setting or settings (Brownson, Colditz, & Proctor, 2012). Implementation strategies have been referenced as implementation drivers which may include staff selection, pre-implementation and on-going training and mentoring, staff evaluation, administrative assistance and system interventions(Brownson et al., 2012; Rabin, Brownson, Haire-Joshu, Kreuter, & Weaver, 2008). New models guiding implementation research are emerging (Aarons et al., 2011; Nilsen, 2015) as efforts have been ramped up to address the lagging utilization of evidence-based interventions and practice. One such model is the Consolidated Framework of Implementation Research (CFIR)(Damschroder & Hagedorn, 2011) which has been utilized in 26 empirical studies primarily guiding analysis. The model, since 2009, has demonstrated usefulness in guiding implementation research

design, implementation construct language and analysis of findings and is supported with web-based resources and technical assistance (Kirk et al., 2016).

Very few studies have examined the effectiveness of current HIV intervention implementation strategies and only one has addressed couples-based behavioral intervention implementation (Witte et al., 2014). There is much opportunity to learn from the largest diffusion effort in the U.S. initiated through the CDC's Diffusion of Effective Behavioral Interventions (DEBI) program, now called High Impact Prevention (Collins et al., 2010a; DANYA, 2015), for which Connect (El-Bassel et al., 2003) remains a best evidenced intervention available for implementation. Best evidence means the intervention met the CDC criteria that includes being tested with a comparison group, have been rigorously evaluated, and shown significant and positive evidence of risk reduction efficacy (i.e., eliminate or reduce sex- or drug-risk behaviors, reduce the rate of new HIV/STD infections, or increase HIV-protective behaviors) or for improving linkage to, retention in, or re-engagement in HIV medical care among persons living with HIV (CDC, 2016). These interventions are considered to be scientifically rigorous and provide the strongest evidence of efficacy. Connect intervention utilization, as part of the compendium of best-evidenced interventions, is supported by funding requests, and the CDC diffusion team offers a 3-day training and technical assistance to CDC-and state health department-funded organizations as well as other locally supported implementers in HIV prevention (CDC, 2015). Training content addresses pre-implementation activities such as decisions about intervention choice and organizational readiness, and implementation content to address knowledge and skill to conduct the intervention and, finally, maintenance content to address quality assurance and monitoring. Currently, there are two capacity-building agencies funded to provide training and technical assistance for organizations building readiness to implement Connect, however, there are only 3 CDC-funded agencies to implement in the US (DANYA, 2015).

HIV prevention and implementation science

Some studies have highlighted barriers to implementing best evidenced interventions and recommended solutions. Recommendations have included the need for improved cost-effective training and initial guidance on the selection and adaptation of appropriate interventions to meet contextual and target population goals as determined by local needs assessment. Other recommendations referenced are the need to address staff buy-in at multiple levels in the adoption process; ongoing reactive and proactive technical assistance and booster trainings to increase self-efficacy in core skills (e.g. facilitation in couples-based intervention modalities); and regular voluntary communications between implementing organizations to facilitate peer sharing, networking and incorporation of a community collaborative process surrounding implementation to ensure relevance and cultural competence (Collins, Harshbarger, Sawyer, & Hamdallah, 2006; Collins et al., 2010a; El-Bassel, Gilbert, et al., 2010). CDC trainings for EBIs often provide the opportunity to share ideas with other implementers as attendees usually come from many states and service contexts. Community-based organizational directors and potential intervention facilitators have been identified to view HIV prevention intervention training as an opportunity for advancing their skills, often attending training without a previously developed commitment to fully implement the intervention as packaged and disseminated. This strategy of prevention skills and knowledge development of staff is counter to the need for planning and commitment to implementation plans prior to attending training (Owczarzak & Dickson-Gomez, 2011; Wingood & DiClemente, 2008).

Mediator analysis to inform the how of implementation strategies

Recommendations have been made to include mediator analysis in research designs to enhance the degree of new information garnered from outcomes studies to generate practical knowledge to inform key elements of interventions (Krull & MacKinnon, 2001; Landsverk et al., 2012; MacKinnon, 2011) and content of training curricula, for example. Mediators assist the field in understanding "how" an intervention works. Mediation analysis findings may identify certain intervention or implementation

strategy components that need to be abandoned or strengthened, as failures to significantly alter mediating variables occur either because the strategy was ineffective or the measurements inadequate. Importantly, mediation can be used to identify proximal outcomes that can be used as a replacement for an ultimate outcome. For example, the measurement of intention to implement an intervention instead of observing actual operationalized implementation. Finally, and most importantly to HIV prevention capacity building and efficiency, mediation analysis provides evidence for how a strategy achieved its effects (MacKinnon, 2011). Identification and validation of ingredients can streamline and improve programs by designing curricula for implementation strategies that focus on effective components (Wandersman, 2012) to strengthen commitment to implementation intention. Due to time limitations, choices are required regarding content and skills practice to be included in training designs, especially as cost of multiple days of training are considered. Analysis of mediators can assist the design of implementation strategies focused on training and technical assistance by identifying active ingredients effecting staff intention to implement EBIs.

Building on outcomes from an RCT to examine the dosage effect and mediators of an implementation strategy

To help address gaps in knowledge regarding implementation factors influencing HIV prevention evidence-based intervention (EBI) implementation, and to inform efforts to build the capacity of communities to adopt couples-level interventions, this study uses quantitative methods with longitudinal data derived from a sample of 253 staff from 80 organizations that provide HIV prevention services in New York State to examine mediators of a training and technical assistance implementation strategy on intention to implement Connect at 6 and 12 months post implementation strategy. Agencies participating in this RCT funded by the National Institute of Mental Health (NIMH) (PI: S.Witte) were trained in either a traditional paper-based version of Connect or multimedia-based version and offered two follow-up technical assistance calls and the option of on-going TA upon request. This study provides important new

data on factors believed to mediate the effects of a training and technical assistance strategy on the intent to implement the Connect intervention. Intent has been shown to be strongly associated with actual implementation of new programs (Ajzen, 1991; Fishbein, 1975; Gollwitzer & Brandstätter, 1997; Webb & Sheeran, 2008) and was examined as a factor on the pathway to the implementation of the Connect intervention. Analysis of the direct dosage effect of the implementation strategy defined in this study was found to be significantly associated with increased intention to implement the couples-based intervention Connect. This finding supported the next step of analysis focused on mediators believed to be associated with this implementation strategy dosage effect. The mediators include individual staff perception of individual and organizational level factors including staff self-rating of self-efficacy to implement Connect, attitude toward intervention characteristics, and perception of the availability of an organization intervention champion. While acknowledging the many known factors associated with implementation informed by the organizational context (Aarons, Ehrhart, Farahnak, & Hurlburt; Aarons et al., 2012; Chaffin, 2006; Dijkstra et al., 2006; El-Bassel et al., 2003; El-Bassel et al., 2005; Glisson et al., 2008; Lehman, Greener, & Simpson, 2002; Miller, Bedney, Guenther-Grey, & Team, 2003; Patterson et al., 2005; Smith & Manfredo, 2011) this analysis narrowed the focus on the important perception of the individual's intention, as individuals contribute to decisions whether or not to adopt and implement Connect within organizations. This contributes to increased understanding of factors that are critical to inform capacity building and implementation designs and further the adoption of this effective strategy to engage those at high-risk for HIV, including HIV discordant, MSM and drug involved couples.

Guided by the Consolidated Framework for Implementation Research, (Damschroder, Aron, et al., 2009b; Kirk et al., 2016) a model for implementation research, that incorporates many theories of which the Diffusion of Innovation (Rogers, 2003), Theory of Reasoned Action (Ajzen, 1991) and Social Cognitive Theory (Bandura, 1986) were highlighted due to their relevance to variables selected for this study. I examined implementation factors taken from staff perception of multiple domains using data from 253 individual practitioners from 80 organizations focused on one primary outcome from the CFIR

(see Table 2) Individuals Involved Characteristic level: staff **intention** to implement Connect a couples-based approach to HIV prevention.

Specifically, this study examined two primary questions:

1) What effect does exposure to the implementation strategy (4-day training plus 2 technical assistance [TA] calls) for Connect, a couples-based HIV/STI prevention intervention, have on staff intention to implement Connect post intervention at 6, and 12 months follow-up taking into account dosage (0-6 days)? And,

2) In what way is the effect of exposure to the Connect implementation strategy mediated by staff perception of 3 CFIR domains: a) Characteristics of individuals involved: self-rating of **self-efficacy (SE)** to implement Connect, b) Intervention characteristics as measured by favorable perception of the **intervention characteristics (IC)** and c) Organizational Process: the staff perception of the availability of an **intervention champion (C)**?

Chapter II:

BACKGROUND

Review of Related Literature and Studies

Scope of HIV prevention in the U.S.

Today, more people in the U.S. are living with HIV than ever before, as those infected are surviving longer, and the number of new infections remains relatively stable (CDC, 2014). More than 650,000 people have died from HIV in the U.S. since the epidemic began in 1981, yet 1.2 million people are living with the virus (CDC). While there have been major successes, especially with availability of new biomedical strategies, it is agreed that innovative behavior change strategies are still needed to stop the spread of HIV and AIDS with new infections remaining steady for more than a decade at 50,000 per year in the U.S. Forty-five percent of new infections occur in the rural South, where HIV-infected patients have lower survival rates and tend to be younger, more rural, African American, Hispanic, and female. While many people with HIV are diagnosed (86 percent), far fewer are engaged in care (40 percent) and are prescribed antiretroviral therapy (37 percent). Only 30 percent of HIV-infected individuals are virally suppressed (the point at which the virus is under control and a person can remain healthy and reduce the risk of transmission)—a share that is even lower among blacks (28 percent) and young people aged 25–34 (23 percent) (CDC, 2014). To better focus prevention strategies toward most at-risk populations efficiently, there is a call for intensified prevention targeted at men who have sex with men (MSM), particularly young African-American (AA) men, Young Men Who Have Sex with Men (YMSM), substance users and AA women.

Evidence-based interventions

For over 30 years, public health researchers have developed and tested interventions to address high-risk behaviors to reduce HIV and other STIs. Many studies have shown the effectiveness of community-, small group- and individual-level interventions while only Connect and an adaption called SMART Couples for treatment adherence have utilized a couples-based approach for HIV prevention (El-Bassel et al., 2005; Fixsen et al., 2005; Kalichman, Belcher, Cherry, & Williams, 1997; Kelly et al., 2000c; Remien et al., 2005). Once new interventions are proven effective the next challenge is their implementation. Only a few studies have examined the effectiveness of current HIV intervention implementation strategies. The CDC's High Impact Prevention (HIP) program, formerly called Diffusion of Effective Behavioral Interventions (DEBI) (CDC, 2006a, 2015; Collins et al., 2006), has identified Connect, upon which this dissertation is centered, as a best evidence-based intervention available for implementation.

Dissemination and implementation science

The field of dissemination and implementation science (D & I)(Rabin et al., 2008) is growing, as recognition of innovative, evidence-based interventions has been identified to address a range of health-related problems (Procter, 2011; Proctor et al., 2009). Dissemination is defined as an active plan to diffuse evidence-based interventions to selected populations through specified channels employing designed strategies (Rabin et al., 2008). It has been an early focus to raise awareness of available interventions to increase adoption, with a recent study identifying 61 D & I models of which 27 were focused on dissemination, compared to 17 on implementation (Kegeles, Rebchook, Tebbetts, Arnold, & Team, 2015). Despite this growing trend in D & I science, D & I studies on HIV prevention in the U.S. remain extremely limited. A recently released guidance from NIH regarding research priorities called for "translational research (i.e., dissemination, implementation, or operational research) to foster and optimize the use of existing efficacious biomedical, behavioral, and social interventions to prevent,

diagnose, and treat HIV infections and to promote access, acceptability, adherence, and continuation along the cascade from prevention to treatment, particularly among those currently underrepresented in such research (e.g., non-injection substance users, men who have sex with men [MSM], and incarcerated individuals). Behavioral and social science can contribute to more effective utilization of scientific findings by determining factors that cause adoption and continued utilization of scientific findings" (Whitescarver, 2015) [(p.28)]. With macro-level support from NIH the field of D & I in HIV prevention should continue to proliferate, with couples-based methodologies offering innovation to fill a gap by engaging highest risk populations: MSM, substance users, criminal justice-involved populations and HIV discordant couples (El-Bassel, Jemmott, et al., 2010). A contribution to implementation research would be examining the effect of training and technical assistance strategies supporting implementation through relevant mediators believed to effect decisions and intention to implement.

Some studies have highlighted barriers to EBI implementation chosen for diffusion and recommended solutions. Recommendations include the need for improved training and guidance on selection and adaptation of EBIs, addressing the need for staff buy-in at multiple levels to adopt the intervention (Aarons, 2006); more cost-effective approaches to training and ongoing reactive and proactive technical assistance; additional trainings to increase core skills (e.g. training to address self-efficacy to facilitate a couple-based intervention); and regular voluntary communications between implementing organizations to facilitate peer sharing and networking and incorporation of a community collaborative process surrounding implementation to ensure relevance and cultural competence. (Eke, Neumann, Wilkes, & Jones, 2006; El-Bassel, Gilbert, et al., 2010; Zayas, Bellamy, & Proctor, 2012). Costs effective analysis for HIV prevention strategies, including behavioral interventions such as couples-based and partner services, have received increasing attention. Cost analysis helpful in supporting policymakers or those charged with HIV resource allocation decisions in several ways. First, it identifies the body of evidence of cost effectiveness for the various interventions and encourages decision-makers to seek local data on the costs and outcomes (Huang, Lasry, Hutchinson, & Sansom, 2015). Intervention

implementation strategies and the training and technical assistance that comprises them carry costs. This study focused on the examination of dosage of an implementation strategy incorporating training and technical assistance and mediators believed to be associated with intention as an outcome as proxy for implementation. Cost of implementing is often examined in terms of the number of training days and whether it is classroom or distance learning and is considered in determining more efficient implementation strategies (DANYA, 2015). This study contributes to understanding the dose effect of in-classroom days of training and the direct and mediated effect on intention to implement, but does not incorporate a distance-learning comparison. Enhancing our understanding of how the number of contacts may impact intention to implement an EBI can inform decisions about strategy designs and associated costs. Of note, the perception of cost of implementing Connect as a barrier was not added to the intervention characteristic mediator scale as it was not found to contribute any additional factor loading. This is discussed in the measurement section.

Couples-based HIV Prevention

Of the 33 couples-based studies identified in a recent systematic review, 27 were identified as biobehavioral, 13 were psychoeducational skills building, 13 examined voluntary counseling and testing (VCT), and only one focused on treatment adherence. Twelve studies included heterosexual couples, and one dealt with MSM. None of the identified studies examined dissemination or implementation factors (Jiwatram-Negrón & El-Bassel, 2014). With 86% of the new cases of HIV being attributed to sexual transmission, MSM (54%) and heterosexual contact (32%) interventions have remained focused on individuals and groups and have largely missed the opportunity to engage intimate, sexual partners in prevention strategies (El-Bassel, Gilbert, et al., 2010). Recent efforts toward the support of implementation of Couples HIV testing and counseling (CHTC) (Allen, 2002; Purcell et al., 2014) and Connect, a couples-based behavioral intervention chosen by the CDC as a “best evidence” intervention, have not been widely adopted in the field. Though national training has been conducted on CHTC and

Connect, implementation is slow to be realized (Beougher et al., 2015). Only three community-based organizations were CDC-funded to implement Connect and 32 for CHTC in the US (DANYA, 2015).

There is strong evidence demonstrating the advantage of a couples-based approach to HIV prevention. If both partners in a HIV discordant relationship know their status, they may enter treatment early, allowing the opportunity of viral suppression and reducing transmission. They may discuss ways to support treatment initiation (PrEP, ART) and the importance of and how to support adherence, as in SMART Couples (Remien et al., 2005). Agreements about monogamy and outside relationships can be negotiated in a safe context. Additionally, studies have shown significant increases in condom use among HIV discordant couples who participated in a couples-based behavioral intervention (El-Bassel, Jemmott, et al., 2010).

With the availability of the high impact biomedical strategies (HIV testing, nPEP, PrEP and TASP), it is important to engage couples who want to know their status together and to assist them with the skills needed to effectively make decisions together about the initiation of medical strategies, and ways to support each other through joint problem-solving. Connect for heterosexual and serodiscordant couples (Hunt, 2013), and its new integrated adaptation informed by a study with AA MSM components (Wu et al., 2011) with new video models representing AA MSM, Transgender, HIV discordant and substance using couples, is being cleared for dissemination in 2016 (CDC, 2015; Stallworth, 2015, Dec.). Additional research is needed to examine adoption and implementation of an integrated approach to couples-based prevention which offers a high impact continuum of services, including CHTC, behavioral skills, biomedical strategies (nPEP, PrEP) and relational support for treatment adherence (TASP) (Remien et al., 2005) in a couple context (El-Bassel, Jemmott, et al., 2010; Jiwatram-Negrón & El-Bassel, 2014; Purcell et al., 2014).

HIV-discordant couples

A large multisite study, Project EBAN (El-Bassel, Jemmott, et al., 2010), with AA heterosexual HIV serodiscordant couples, demonstrated effectiveness in increasing condom use and lowering risk behaviors (El-Bassel, Jemmott, et al., 2010; Jiwatram-Negrón & El-Bassel, 2014; Purcell et al., 2014). This intervention has been utilized only in a research context. While MSM represent an estimated 2% of the US population, in 2010 MSM accounted for 63% of new HIV infections. MSM have an estimated infection rate at least 59 times that of other men and more than 52 times greater than women (Purcell et al., 2014). This high prevalence along with unidentified HIV infections leads to a higher rate of HIV discordancy than in other populations. HIV prevention with MSM has primarily utilized individual and groups methods of delivery, while an estimated 33-67% of infections among MSM is contracted from their primary sexual partner (Purcell et al., 2014). A couple approach to prevention has been shown effective with heterosexual couples and in one AA MSM pilot (Wu et al., 2011), in risk reduction, increased condom use, reduction in drug use, as well as treatment adherence (El-Bassel et al., 2003; Jiwatram-Negrón & El-Bassel, 2014; Remien et al., 2005; Wu et al., 2011). As previously stated, a large segment of innovative treatment and prevention strategies across problem areas have yet to materialize in real-world implementation. Implementation research examining facilitators and barriers on multiple levels, models and strategies supporting implementation will serve the field to answer critical questions needed to enhance uptake of evidence-based practice and interventions (Brownson et al., 2012). The examination of training and technical assistance content and dosage addressing effect on intention to implement is one inquiry to support the development of combination or bundled (Aboelela, Stone, & Larson, 2007) strategies to support implementation.

CDC's High Impact Prevention and the Diffusion of Evidence-Based Interventions

The Interactive Systems Framework for Dissemination and Implementation (ISF) is a multi-system framework that can guide research-to-practice efforts by building and supporting the work of three

interacting systems: the Prevention Delivery, Support, and Synthesis and Translation Systems (Wandersman et al., 2008). While there are numerous ISF models and services designed for HIV prevention, the CDC High Impact Prevention (HIP) is the largest translation program in the U.S. The ISF directly links researchers, capacity building providers or those trained by researchers in an exchange of ideas focused on successful implementation. Until 2011, the CDC's HIV/AIDS Prevention Research Synthesis (PRS) Project named 74 evidence-based interventions (EBIs) addressing sexual and injection related HIV risk. There is currently one EBI for heterosexual couples, Connect, and none for MSM (El-Bassel, Gilbert, et al., 2010; Jiwatram-Negrón & El-Bassel, 2014; Purcell et al., 2014). Currently, there is an adapted version of Connect called Connect ^{HIP} integrating outcomes with African American MSM, Transgender and HIV discordant heterosexual couples found in Connect with Pride (Wu et al., 2011) being revised and in preparation for dissemination later in 2016. Connect^{HIP} remains a supported intervention through the CDC's ISF framework and training, and TA efforts to build community capacity to deliver this intervention. The implementation plan, of which I led, was informed by findings of the parent study (Witte et al., 2014), and, potentially, the outcomes of this dissertation.

Under current HIP/DEBI programming, over 28,583 individuals have been trained in 66 interventions, strategies and supervision models incorporation individual, group and couples-based approaches since 2002 (DANYA, 2015). Since this study focuses on an implementation strategy for a couples-based approach, Table 1 describes the current state of CDC sponsored training in couples-based HIV prevention methodologies in the US. For Couples HIV Testing and Counseling (CHTC), 1,091 have been trained, and for Connect, the first couples-based HIV prevention behavioral intervention being disseminated, 92 have completed training. Training is highly standardized while technical assistance that follows is generally individually tailored to best meet the needs of agencies as they move through stages of implementation. Plans typically involve providing reactive technical assistance (responding to requests for implementation assistance when asked by the agency) and may include: 1) technical assistance – the provision and/or facilitation of culturally relevant and expert programmatic, scientific, and technical

advice (mentoring/coaching) and support; 2) training – curricula development, delivery of curricula and coordination of training activities to increase the knowledge, skills and abilities of trainers, educators and service providers; and 3) information dissemination – distribution and sharing of relevant and current HIV prevention information (reviewed by peer materials review committees prior to dissemination) through print materials, presentations, websites, and mass media (Fenton, Wolitiski, Lyles, & Aral, 2009). Barriers to implementation and lessons learned for four interventions being disseminated by HIP targeting HIV positive individuals were identified from data collected through the CDC's technical assistance request system and from one of their funded CBA providers, UT Southwestern (Collins et al., 2010a). Barriers included difficulty recruiting people into the intervention, lack of resources such as meeting space or video equipment, staff turnover of those trained in the intervention, and poor buy-in from the agency leadership. Those with barriers were significantly less likely to implement the intervention. More studies of this nature are needed to improve selection of HIV prevention EBIs to engage HIV discordant individuals and couples, to inform training curricula, dosage and TA activities, and to develop cost-effective strategies to shepherd successful implementation. Staff with a previous history of receiving technical assistance from organizations serving HIV+ clients anticipated fewer potential barriers to adopting an evidence-based intervention (Kelly et al., 2000a). The implementation strategy utilized in this study contained training and technical assistance content, describe later, that addressed these barriers during an implementation and maintenance module.

Table 1. Completed Couples-based HIP Trainings by Agency Type (1/1/2002 to 7/31/2015)*

Interven-tion	Train-ings	Partici-pants	Agencies	CBOs	Health Dept.	Other (clinics, universities)	CBO Partici-pants	Health Dept. Participants	Other Participants (clinics, universities)
CHTC	67	1091	464	177	97	190	508	194	389
Connect	10	92	45	19	7	19	49	16	27
Total	1852	28583	11221	5994	1540	3687	17417	3512	7654

*DANYA International Inc. report accessed 8.28.15

Studies are needed to examine the dosage of in-class room trainings with or without technical assistance, as well as, comparative effectiveness of in-classroom versus distance learning on couples-based facilitation skills, self-efficacy and intention to implement interventions to inform cost effective implementation strategies (Collins et al., 2010a; Johnson et al., 2006; Witte et al., 2014). This study contributes to our knowledge of training and TA dosage effect on intent to implement and may aide funders' decision-making regarding training designs and methods, including future investment in distance learning options.

Training plus technical assistance as an implementation strategy

A ground-breaking study Kelly et al. (2000a) captured insights into implementation methods comparing training, technical assistance and manual-only capacity building and the impact on adoption of HIV prevention interventions. In this study, the researchers utilized external consultant technical assistance providers. Fixsen et. al. (Fixsen et al., 2005) through a synthesis of the literature on implementation, has provided clear insight into core implementation components needed to effectively support the adoption of an intervention with fidelity and sustainability. We agreed during the parent study (Witte et al., 2014), our implementation strategy should incorporate an integration of support components

(e.g. training, technical assistance and tools) which lends itself to a stronger model of implementation support (Wandersman, 2012). Beginning with tools developed and tested during the initial trial of Connect (El-Bassel et al., 2003) and revised during the replication process with the CDC (Witte, S. PI). Tools alone are critically important to facilitate implementation and support fidelity, but not fully sufficient to ensure quality implementation (Kelly et al., 2000a). The effectiveness of tools can be enhanced by including their use during an implementation strategy training focused on how to use and interpret findings of process and outcome tools. Tool training, such as the use of logic models for intervention implementation, serves to support self-efficacy toward implementation and to answer questions about why core elements are critical to intervention outcomes. Training is often cost-efficient but not sufficient for ensuring actual utilization of an EBI. Training designs can be enhanced with the inclusions of individualized coaching during the in-class designs, as well as, during technical assistance and consultation follow-ups (Fixsen, Blase, Naoom, & Wallace, 2009).

Training designs have been found to be effective when addressing four key components. The first focuses on knowledge and consists of exploring the theory or rationale for the new skills, strategy or intervention. Additionally, training needs to involve facilitator modeling of the new skills – ideally capturing real world examples of potential implementation. The third component is the opportunity to practice the skills and content of a new strategy or intervention. Finally, peer coaching, the fourth component, is the collaborative work of implementers in planning to implement the training content effectively. Quality assurance/quality improvement (QA/QI) reinforces the proper use of the tools, training, and TA for quality performance (Bandura, 1986; Joyce, 2002). In addition to an organization's administrator choice of the most appropriate staff to be trained to conduct an intervention, the impact of coaching during training, supervision and practice post-training with internal versus external change agents have been identified as factors effecting adoption (Wandersman, 2012). A study of the mPowerment intervention implementation for MSM identified that the entire context in which an EBI occurs affects implementation (Kegeles et al., 2015). Recommendations included the need to focus

capacity-building efforts on getting individuals at different levels of the HIV prevention service system to agree on understanding and support in a program's goals and methods. For a Prevention Service to be most effective, it must address facilitators or barriers to implementation, address the right people, and use modalities to convey information that are acceptable for users of the system (Kegeles et al., 2015). Pre-implementation training can begin to address these recommendations in preparation for the program. Self-efficacy can be promoted during training and in post-training technical assistance events and practice, especially with the support of an organizational intervention champion.

Determinants of implementation

Three aims have been identified in the use of theoretical approaches in implementation science and the five categories of theories, models and frameworks that would be useful in studying adoption of couples-based HIV prevention (Nilsen, 2015). Under an influencing implementation outcomes frame, for example, one construct is acceptability/feasibility which can be found under a determinant frameworks. The CFIR that guided this study falls under this category. This example of a framework demarcates types (also known as classes or domains) of determinants and individual determinants, which may act as barriers and facilitators (independent variables) that impact implementation outcomes (dependent variables). The overarching aim is to understand and/or explain influences on implementation outcomes, e.g. predicting outcomes or interpreting outcomes retrospectively. Studies have identified the strong association between an innovation's characteristics defined by DOI theory as perceived by potential adopters and the likelihood of utilization of that innovation (Aarons, 2005; Smith & Manfredo, 2011). Studies are needed to examine the HIV prevention staff's attitude and perceptions regarding needed skills and resources impacting their self-efficacy to implement a particular intervention (Owczarzak & Dickson-Gomez, 2011). Training designs that target enhancing behavioral capabilities incorporate both relevant knowledge and skills to perform a given behavior and to promote mastery. Targeted training and technical assistance implementation strategy design may enhance cost-efficiency for implementation outcomes.

Cost effective analysis for HIV prevention should include an assessment of not only the prevalence of HIV in a particular context but also consider costs related to the particular context, including the availability of training resources (Huang et al., 2015). Implementation strategies should not only address pre-service delivery training components but also post-training supervision and coaching needs (Fuller et al., 2007) to conduct couples-based approaches as a new modality, as well as, how to design policies and structures to facilitate this method's sustainability (e.g. funding and reimbursement issues, confidentiality policies) in real world and diverse settings.

The organizational context and culture is an important determinant of EBI adoption (Aarons et al.; Aarons et al., 2012; Chaffin, 2006; Glisson et al., 2008; Jung, Chow, & Wu, 2003; Packard & Shih, 2014; Stetler, McQueen, Demakis, & Mittman, 2008). Perception by staff of the intervention's complexity, the perception of the need for and availability of advanced supervision and the cost effectiveness of required sessions and dosage if communicated to supervisors and administrators may cause administrative decision-makers to distance themselves from a couple's approach. Training that incorporates an administrator and direct facilitators of an intervention can address these potential barriers in pre-implementation. Transformational leadership and intervention champions (Aarons & Sommerfeld, 2012) welcoming innovation, organizational culture (e.g. role overload, role conflict, emotional exhaustion, training support) and organizational policies toward EBI should be considered to better understand adopters for couples-based approaches, and be addressed directly in training and TA content (Collins et al., 2006; Owczarzak & Dickson-Gomez, 2011). Organizational leadership experiencing funding constraints and mandates for targeted services may have difficulty envisioning the introduction of dyadic prevention sessions, especially in a fast-paced environment such as a clinic (Witte et al., 2014). A strong partnership with intervention developers, disseminators and the community can inform implementation strategies and relevant content to enhance successful implementation of an innovation like Connect, couples-based prevention (Czaja, Valente, Nair, Villamar, & Brown, 2016). Training, pre-implementation

activities and follow-up technical assistance are opportunities to examine organizational factors that can facilitate or inhibit implementation.

An extensive review (Powell et al., 2012) of implementation strategies, which are activities designed to promote implementation of a new practice, provided a useful glimpse of the range of implementation strategies that have been utilized and studied. This compilation of 68 implementation strategies provides an opportunity for applied research to examine implementation strategies on multiple levels and that are tailored to an individual context and possibly bundled (Aboelela et al., 2007) in combination approaches for efficiency and effectiveness (Powell et al., 2012). The Connect training and TA implementation strategy incorporated a combined approach of training and technical assistance with content that addresses the individual implementer and activities for organization preparedness.

Multimedia Connect Implementation Parent Study

The Multimedia Connect Project (Witte et al., 2014) compared Connect implementation following dissemination of a traditional, manualized package of Connect, versus the state of the art Internet-based Multimedia Connect with 253 staff at 80 CBOs/organizations across New York State. Over 18 months following the training, at least one study participant from 13 (33%) of the web-based arm and 19 (48%) from the traditional arm reported some program implementation; 15-16% completed one complete cycle of the program, however, a full cycle and sustained implementation was limited, with 6 (3%) at 6 month, 7 (3%) at 12 month and 17 (8%) at 18 month staff completing full cycles of the intervention.(Witte et al., 2014). Of note, most staff had not implemented services with couples before. Their perceived enthusiasm and positive training evaluations point to the usefulness of further examination to understand how or if the training and TA combination strategy impacted mediators that may influence their intention to implement. Findings suggest the need for additional training content on couples-based approaches for recruitment and engagement, and technical assistance for pre-implementation planning and assistance to integrate a new method within an organization's context. More inquiry into administrators, intervention

champions (Damschroder, Banaszak-Holl, et al., 2009) and staff assessment of organizational readiness to adopt innovative strategies needs to be conducted (Witte et al., 2014).

In summary, couples-based HIV/STI prevention interventions have shown to be efficacious in reducing HIV transmission by enhancing condom use, reducing sexual and drug sharing risks and increasing adherence to HIV treatment regimens (El-Bassel, Gilbert, et al., 2010; El-Bassel et al., 2001; El-Bassel et al., 2003; El-Bassel et al., 2005; Purcell et al., 2014; Remien et al., 2005). In spite of this evidence, only three agencies in the US are funded by the CDC to implement the intervention (CDC, 2015; DANYA, 2015; Witte et al., 2014). The Multimedia Connect Project found that 32 (40%) of the 80 agencies implemented at least one session of Connect, however a full cycle and sustained implementation was limited, with 6 (3%) at 6 month, 7 (3%) at 12 month and 17 (8%) at 18 month staff completing full cycles of the intervention (Witte et al., 2014). Self-efficacy and intention to implement new behaviors and innovations is known to be associated with adoption of new programming and behaviors. When the perception of intervention attributes are favorable and support for addressing barriers (Kegeles et al., 2015) is available from both external and internal agents, implementation is improved (Fixsen et al., 2005; Wandersman et al., 2008). Cost effective strategies to training are in demand questioning the length of training needed to meet goals and whether classroom or distance learning can be utilized in combination. To my knowledge, research at the staff-level examining these factors has not been conducted for couples-based prevention. Examination of the effect of the Connect training and TA implementation strategy and dosage effect on intention to implement and mediators associated would further our understanding of needed training content and dosage and fill this gap in the literature. Greater understanding of the barriers and facilitators of adoption of a couples-based behavioral intervention can inform training and technical assistance content to support the field as they target MSM, HIV-discordant and drug using couples in HIV testing, PrEP initiation, ART adherence and drug treatment services critical to HIV/STI prevention. This quantitative study design builds on the RCT Multimedia Connect focusing on exposure to an implementation strategy using a relevant implementation framework, the

CFIR, to guide the choice of variables and analysis. It targets individual staff as the unit of analysis and their perceptions of potential mediating factors impacting the effect of the training and TA implementation strategy on intention to implement the Connect, couples-based HIV/STI prevention intervention.

Conceptual Framework

This study is guided by a multi-level integrated framework, Consolidate Framework for Implementation Research (CFIR)(Damschroder, Aron, et al., 2009b) (see Table 2) that incorporates constructs from three classic theories --Diffusion of Innovation (Rogers et al., 2005), Social Cognitive (Bandura, 1986) and Theory of Planned Behavior (Ajzen, 1991) informing variables to be examined in this study. The CFIR is composed of five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Eight constructs were identified related to the intervention (e.g. evidence strength and quality, four constructs were identified related to outer setting (e.g., patient needs and resources), 12 constructs were identified related to inner setting (e.g., culture, leadership engagement), five constructs were identified related to individual characteristics, and eight constructs were identified related to process (e.g., plan, evaluate, and reflect). I propose a focus on individual staff perceptions as key informants to organizational decisions about utilization of EBIs with variation in this sample of designated administrators and staff facilitators.

The three CFIR domains I utilized for this study targeted by content of the Implementation Strategy (training and TA intervention) believed to Effect intention to implement include: (1) **Inner setting** a) *individuals involved* that emphasizes factors related to the characteristics and their experience and knowledge of the innovation that leads to **self-efficacy** to implement, and b) Organization: **Process** which can include an **intervention champion**; and 3) **Intervention characteristics** which include those attributes informed by DOI theory Evidence strength & quality or observability, Relative advantage, Complexity, Trialability, and Compatibility. (See Table 2).

These CFIR encompasses DOI, SCT and Theory of Planned Behavior (TPB) constructs associated with adoption and implementation of EBIs. While the CFIR is an integrated framework encompassing contributions from 19 theories, frameworks or models informing implementation. I chose domains and the theories defining constructs included in the Connect training and TA implementation strategy believed

to effect intention and eventual implementation. Below follows a description of DOI, SCT and TPB constructs utilized in this study incorporated in the CFIR.

Mediators

DOI Components influencing initial adoption process: Intervention Characteristics

The Diffusion of Innovations (DOI) theory guides the process through which an innovation (any idea, program, practice perceived as new) is communicated through channels over time to members of a system (Dearing, 2009; Rogers, 2003). The five major elements in DOI: 1) innovation (e.g. Connect) the first couples-based HIV/STI prevention EBI disseminated by the CDC HIP model); 2) adopter (e.g. agencies and staff implementers); 3) social system (funders, staff, organizations and community joined in HIV prevention); 4) individual adoption-process (awareness, persuasion, decision, implementation, continuation); and 5) diffusion system – the external change agency and paid change agents (CDC capacity building providers, researchers for technical assistance and content experts).

DOI posits that one predictor of adoption is the individual level users' endorsement of five attributes of the innovation: relative advantage, compatibility, complexity, trialability and observability. Rogers (Rogers et al., 2005). There is disagreement among researchers concerning whether there are five distinct attributes or rather combining attributes better explains variance related to intervention characteristics (Pankratz, Hallfors, & Cho, 2002). A score of "favorable" perception of the intervention characteristics has been utilized to examine this domain on innovation adoption as outcome (Scheirer, 1990) and is utilized for this inquiry. Directly associated with perceptions toward an innovative practice such as couples-based interventions is outcomes expectancy. It can be defined as the motivation (outcome expectancy) among agency staff and decision makers to acquire a program. Factors associated with this construct are numerous. The implementer's perception of the innovation's fit with its norms and values, the assessment of risk to implementation and, as mentioned earlier trialability, evidence of effectiveness to fill a gap in service, relevance and ease, and cost effectiveness, observability for couples-based HIV

prevention, trialability and complexity in the agency context would be expected to yield increased intention to implement Connect and are important determinants of adoption or its intent (Chor, Wisdom, Olin, Hoagwood, & Horwitz, 2014). Studies have found association between the provider's openness to innovative practice and its implementation (Smith & Manfredo, 2011).

Individual Implementer characteristic: Self-efficacy

Self-efficacy and Social Cognitive Theory (SCT)

Self-efficacy is the strength of belief in one's own ability to complete a task or reach a goal (Bandura, 1986; Fishbein & Ajzen, 1977). It incorporates both acquisition of needed skills and confidence in one's self to implement the skills in service of the behavior. Social Cognitive theory (SCT) provides guidance to examine individual-level attitudes toward evidence-based intervention (specifically couple-focused) and self-efficacy or confidence in the skill needed and their association to the couples-based intervention adoption. Kelly et al. (Kelly, 2002; Kelly et al., 2000a; Kelly et al., 2000c) conceptualized the process of successful technology transfer of HIV prevention within the framework of cognitive-behavioral theory (Bandura, 1986; Kelly et al., 2000c). This work informed the training and TA combination utilized in this study implementation strategy design described in more detail page 37, Implementation Strategy. From this perspective, adoption of a new program occurs when (1) there is motivation (outcome expectancy or intentional goals) among agency staff to acquire the program, and sufficient resource capabilities to enact it (2) skills needed to implement the program are acquired through instruction, modeling and rehearsal opportunities (self-efficacy); (3) organizational staff and leadership build collective self-efficacy for achieving success in offering the program and perceive positive outcome expectancies for its use; (4) feedback and reinforcement are provided during early implementation phases; and (5) adoption of new programs result in support for other individuals and organizations (champion). SCT may be integrated with diffusion of innovation theory in that the attributes at the individual level predictive of adoption are consistent with SCT constructs of "outcome expectancies." Additionally, SCT

purports learning by observation and mastery through shared or group learning. Theorist have highlighted the importance of lowering uncertainty about an innovation, efficiently done when knowledge is shared by those with greater experience with the innovation and through an organization's knowledge cross fertilization (Liu & Hart, 2011).

Uncertainty has been defined as the difference between the amount of knowledge required to perform a task and the amount of knowledge already available to an implementer (Galbraith, 1974). It is expected that demonstration of knowledge acquisition, an integral component of self-efficacy, would lower uncertainty leading to greater intention and ultimate adoption of an innovative practice. Self-efficacy has also been associated with training outcomes, mediating adjustments to new employment and to attempting new tasks (Saks, 1995) This study focused on an implementation strategy composed of training and technical assistance designed to impact self-efficacy through knowledge and skills building, staff perception of intervention attributes expected to lower uncertainty about the couples-based interventions' fit and relevance to the client's served by their organization and finally, the availability of an invention champion and is informed by theory and constructs incorporated in the CFIR (See Table 2 for domains and variables).

Social Cognitive Theory (SCT) also emphasizes learning by observing. Studies have identified the importance of cross knowledge or the sharing of knowledge within a learning community (Liu & Hart, 2011) as having impact on perceptions of an intervention's relative advantage, as well as, building a shared organizational self-efficacy. The training for Connect and the Connect intervention both utilize modeling and practice to build new skills toward self-efficacy. According to Bandura's theory, people with high self-efficacy, or those who believe they can perform well are more likely to view difficult tasks as something to be mastered rather than something to avoid (Bandura, 1986). The confidence that comes with skills building on a new intervention or method, such as Connect, can allow new implementers to address unpredictable challenges flexibly, with greater sense of control and with less dread of risks. As

mentioned earlier, the implementation strategy (Connect training and TA) core components are also informed by SCT (Bandura, 1986) and Core Implementation Components identified by Fixsen et al (Fixsen et al., 2005) . These included 1) exploring the theory or rationale for the new skills, strategy or intervention, 2) training involving facilitator modeling of the new skills, 3) practice of the skills and content of a new strategy or intervention, and 4) peer coaching and expert feedback with shared learning with fellow implementers from within the organization and with other organizations attending the training.

Motivation for change includes not only outcome expectancies but an assessment of one's own capacity (self-efficacy) which undergirds goal setting toward the adoption of new behaviors (Aarons, 2005; Bandura, 1986; Remien et al., 2005). An emergent intention to implement innovative, evidence-based interventions and methodologies can be examined as a factor for eventual adoption of EBIs. To my knowledge, there are no studies to date that examine the association between intentions to implement as mediated by self-efficacy toward couples-based intervention at the individual level.

Outcome variable

Intention to implement a new behavior

According to the Theory of Planned Behavior(Fishbein, 1975), intention to perform new behaviors of different kinds can be predicted with high accuracy from perceptions toward the behavior, norms, and perceived behavioral control or self-efficacy; and these intentions, together with perceptions of behavioral control, account for considerable variance in actual implementation of a new behavior (Ajzen, 1991; Eiraldi, 2014). Goal intention has been defined as those intentions associated with a specific goal attainment such as 'I intend to conduct x." Achievement of the intended goal has greater likelihood when accompanied with implementation intentions, meaning planned strategies to address barriers to the goal (Gollwitzer & Brandstätter, 1997). This is relevant to EBI implementation as antecedents to full implementation of a new behavior or program include skills building toward self-efficacy and positive

valuation of the program or behavior (Intervention Characteristics) which is associated with the intention to conduct the new behavior or program (Ajzen, 1991; Fishbein & Ajzen, 1977; Gollwitzer & Brandstätter, 1997; Webb & Sheeran, 2008). As the literature has highlighted, the entire ecological prevention system impacts decisions about implementation. Further inquiry is needed to inform supportive strategies to influence adoption of couples-based prevention shown to be efficacious. Persistent barriers, if not addressed, can lessen intention to implement. These barriers pose an opportunity for external change agents often enlisted for training and TA, and for intervention champions and supervisors (Damschroder, Banaszak-Holl, et al., 2009; Eiraldi, 2014) embedded within an organizational system.

Organizational domain: Process mediator

Champion

Successful implementation is believed to require active change strategies aimed to address individual and organizational level utilization of an intervention, as designed (Damschroder, Aron, et al., 2009a). While the relevance of a champion in adoption of EBIs has been established (Rogers, 2003; Rogers et al., 2005) it has not yet been examined as applied to couples-based adoption and implementation. A champion is seen as an individual who dedicates themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the intervention may provoke in an organization (Shane, 1995). Studies have shown the presence of one or more champions is an important factor associated with implementation of a new program by providing leadership, enthusiasm and expertise (Shane, 1995), but champions alone were inadequate to bring about change. Few studies have gone beyond the presence or absence of a champion, sometimes called opinion leader. Rating champion quality and effectiveness (Aagaard, Gonzales, Camargo, & Auten, 2010; Damschroder & Lowery, 2013) would provide depth of understanding for this under-utilized implementation construct. Incorporating a champion or champions (Damschroder, Banaszak-Holl, et al.,

2009) along with other implementation strategies, like the Connect training and technical assistance implementation strategy, are likely to increase intention to implement. This study sought to answer the first step regarding staff perception of the availability of an intervention champion and whether this mediated the implementation strategy dose on intention to implement.

Control variables

In order to best answer the research question examining the dose effect of the implementation strategy on intention to implement and on three mediators on the path to intention, we controlled for potential confounding sociodemographic variables including gender and race/ethnicity. Informed by the related literature and empirical evidence from the parent study and exploratory analysis for this study, we controlled for age, tenure in the HIV field and at the agency, role as administrator or facilitator, and previous experience facilitating DEBIs given the increased likelihood to have experienced EBI implementation and subsequent perception of self-efficacy. Individual staff who were older and obtained higher levels of education have reported less confidence in the ability of their agency to deliver an intervention, while those with higher education have been found associated with supporting of evidence-based treatment implementation (Ogborne, Wild, Braun, & Newton-Taylor, 1998), and in our exploratory findings college education ($p=<0.0001$) and graduate school ($p=0.003$) were associated with intention to implement in the next six months (See page 61). The participant's role within the organization has been associated with perceived number of barriers to implementing evidence-based interventions. Both prevention program directors and paid staff members were likely to perceive more barriers when compared with volunteers. Administrators were less confident in the organizations ability to implement the evidence-based intervention than frontline staff, while frontline staff were more likely to perceive administrators as not supportive of implementation of new interventions (DiFranceisco et al., 1999). The number of years of service within an organization; longer tenure with the servicing organization was associated with the perception of more obstacles to implementing an intervention (DiFranceisco et al.,

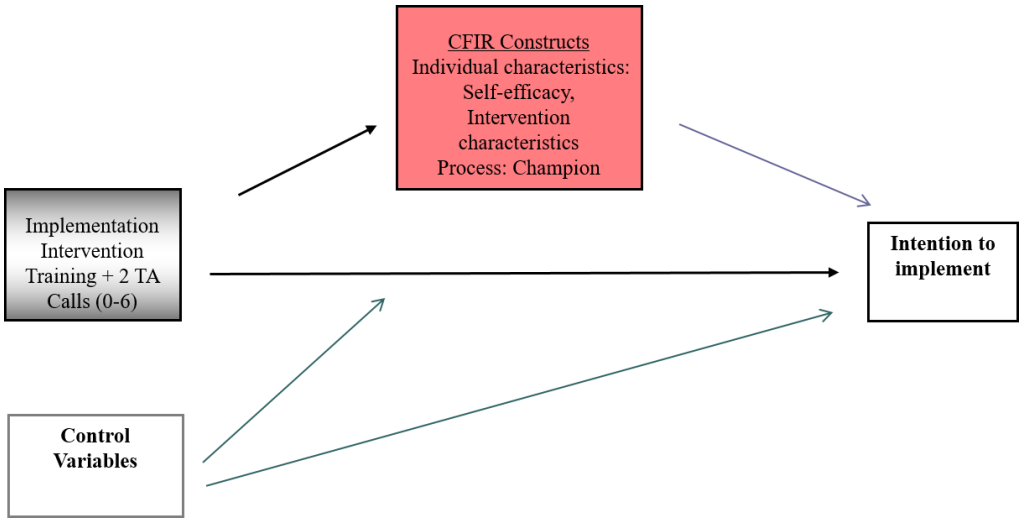
1999). Staff in early career training, including internships, have been found to be more open to learning new interventions (Aarons, 2004) which may impact their response related to intention to implement the Connect intervention. Reported in the sample descriptive findings described on page 51, we found a statistically significant positive association with the staff attitude toward evidence-based HIV prevention interventions and their implementation of at least 1 evidence-based HIV prevention intervention (p=0.002). Age was positively associated with having been trained in at least one evidence-based HIV prevention intervention (p=-0.05). Having previous experience and training in evidence-based interventions may impact intention to implement Connect and potential relationship with the mediators of interest, supporting the relevance of these factors as control variables. Additionally, in our exploratory analysis, we found that baseline report of intention to implement was significantly associate with intention at 12 months (p=0.006), but not at 6 months (p=.03). To focus on the examination of the implementation strategy dosage on our mediators we control for baseline intention noting a significant relationship at the 12 month follow-up.

Randomized condition assignment was controlled for to take into account any differences experienced by the method of Connect intervention delivery or enhanced multimedia training videos offered for the Multimedia arm participants (Witte et al., 2014), and for intention to implement Connect in the next six at baseline to allow examination of the dose effect on intention following the implementation strategy.

CFIR Constructs and domains

The CFIR constructs guided the selection of variables at multiple levels (Intervention Characteristics, Inner level and Individual Characteristics and Organizational Process, see Figure 1, Table 2) to examine and illuminate study findings from AIMS targeting perceptions of the individual staff member. The four AIMS provide examination of mediators of a training and technical assistance implementation strategy by dosage and its effect on individual staff intention to implement Connect.

While the theory strongly supports the pathway from intention to actual implementation this study did not conduct quantitative testing of mechanisms or mediators on direct implementation as the numbers were too few to examine.



Control Variables: Gender, age, education, race/ethnicity, tenure in HIV field, condition assignment, baseline intention score, role with Connect, facilitated DEBIs

Figure 1. Conceptual Framework of Mediational Analysis Guided by CFIR Domains: (1) Individual Characteristic Self-efficacy, (2) Intervention Characteristics, and (3) Champion with Intervention dosage effect on Intention to Implement Connect (couples-based prevention)

Table 2: CFIR Theoretical Constructs and Corresponding Variables

THEORETICAL COMPONENTS	IMPLEMENTATION CONSTRUCTS	VARIABLES EXAMINED
Intervention Characteristics (IC)		
	IC five item favorable perception score	Mediator, control and descriptive
Evidence strength & quality or observability	Staff's perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	**Mediator:** Connect is effective at teaching clients about HIV prevention
Relative advantage	Staffs' perception of the advantage of implementing the intervention versus an alternative solution.	**Mediator:** Including Connect in our prevention programming improves our ability to reduce risk among heterosexual couples
Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement	**Mediator:** Connect is easy to understand and easy to conduct
Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems	**Mediator:** Connect is a program that fits (or blends) well with the culture, needs, other services as well as the mission of our organization
Trialability	The ability to test the intervention on a small scale in the organization], and to be able to reverse course (undo implementation) if warranted.	**Mediator:** I have the time and opportunity to conduct Connect for practice first before I actually work directly with clients on it
Inner Setting		
Structural characteristics	The social architecture, age, maturity, and size of an organization	Descriptive data utilized to describe the Agency size, # staffing, #clients served in multi-sessions, # of DEBIs offered
Individual Characteristics		
Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	**Mediator**: I am able to implement CONNECT successful (*self-efficacy*)
Other personal attributes	A broad construct to include other personal traits such former training on EBIs, facilitation of EBIs, education, years in service	Control variables: Gender, age, education, race/ethnicity, tenure in HIV field, condition assignment, baseline intention score, role with Connect, # DEBIs facilitated
Organizational Process		
Champion	Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation], overcoming indifference or resistance that the intervention may provoke in an organization.	**Mediator**: My agency has a *champion* for Connect

Chapter III:

METHODOLOGY

Study Design

Design, recruitment and sampling

The data for this study is derived from the Multimedia Connect Project (PI: Dr. Susan Witte). It was funded by the National Institutes of Mental Health (NIMH) and conducted between 2007- 2012 by the Social Intervention Group at Columbia University School of Social Work (Witte et al., 2014) . For this study I served as a co-investigator and co-facilitated all intervention trainings and technical assistance calls. The Multimedia Connect Project RCT, community-based participatory, mixed methods research design, compared Connect implementation following dissemination of a traditional, manualized package of Connect, versus the state of the art Internet-based Multimedia Connect to 253 staff at 80 CBOs/organizations across New York State. The parent study RCT randomly assigned 40 matched pair organizations to receive the Multimedia intervention and training package (Multimedia) or the original, manualized-paper-based Connect intervention and training package (Traditional).

Recruitment and sample

80 agencies providing HIV services in New York State were recruited. Eligible agencies had 501c3 status, provided HIV prevention services to heterosexual men and women, and agreed to send at least one participating staff member for training on Connect. 145 agencies identified from a list of state-funded community service providers (CSPs) and multiservice agencies (MSAs) as well as, non-state funded agencies identified through 5 Web sites of HIV services coalitions were screened. The final sample was made up of 80 agencies (55% of those contacted) who met the inclusion criteria and were willing to participate. Some agencies reported they did not serve couples or did not have the staff available to allocate to the study.

Up to 6 staff from each agency were allowed to participate in the training and technical assistance and study follow-ups. 253 staff were enrolled in the study. Each enrolled agency was asked to identify one 'administrator' and up to 5 intervention facilitators to participate. The label of facilitator was chosen to capture the nature of the intervention implementer as a staff trained to utilize the manualized intervention with its content and skills building with couples rather than what is generally perceived as a traditional couples therapist. Participating staff completed baseline assessments administered through a web-based, encrypted program prior to training. We did not replace participating staff who left the agency, but kept all randomized participants in the study following an intent-to-treat (ITT) (Greenland, Greenland, & Lanes, 2008) design whether they remained at their original agency or left, monitoring if they implemented the program at their new agency (Witte et al., 2014).

Randomization

For the parent study, a matched pair approach to randomization (40 pairs) to two conditions was employed, first matching agencies on two stratification factors believed would influence the adoption of the intervention: 1) the number of full and part-time staff providing HIV prevention services; and 2) the number of clients receiving multisession HIV prevention interventions in the prior year, and then assigned one of the two agencies within each pair, or cluster, randomly to each condition (Witte et al., 2014). Agencies within each pair were then assigned to either the traditional or the multimedia dissemination package. For this study, we combined all participants from both assigned arms having examined their comparability in the parent study and saw no significant differences between groups (Witte et al., 2014). Additionally, we controlled for arm assignment in the analytic model.

Implementation Strategy—Training and Technical Assistance

Agencies were provided: 1) the original, manualized (paper-based) Connect and manualized facilitator curriculum with a 4-day, face-to-face structured orientation and training. Participants were then offered planned, investigative-team-initiated telephone consultations to provide TA at 2 and 4 months

following the training workshop; or 2) Multimedia (web-based) Dissemination package which was hosted on the internet with password protected access. The Multimedia agencies were provided the Multimedia Connect and Multimedia facilitator curriculum with a 4-day, face-to-face structured orientation and training. The training curricula covered the same core components, however, the Multimedia training included accessing additional video modeling on the web-based tool. The Traditional, paper-based version, included some video modeling on a DVD interface tool which could be accessed through a computer. Both conditions were provided opportunities for scaffolded learning. Participants were then offered planned, investigative-team–initiated telephone consultations to provide TA at 2 and 4 months following the training workshop. Agencies were provided scheduled training once or twice per month on a rolling basis for groups of 15–20 participants from up to 5 agencies from the same condition (manual-based vs. multimedia). Agencies were encouraged to request additional 'reactive' telephone or on-site TA at any point throughout the trial.

Guided by the core components of implementation (Fixsen et al., 2009) and SCT (Bandura, 1986) discussed earlier, and to address key mediators examined in this study (see Table 3), the training curricula design (Hunt, 2010) and technical assistance calls format and agendas provided recommended pre-implementation discussion, including assessment of staffing needs for training, assessment of staff skills for implementation, resources and budgeting, buy-in from agency and community for recruitment and the usefulness of supervision and an intervention champion. It included an overview of the Connect intervention core components and theory behind its development and evidence of its efficacy to promote a favorable perception of the intervention. Core intervention components were reviewed and modeled by the trainers, and all study participants role-played sessions to build self-efficacy with strength-based coaching and feedback. Peer learning was incorporated in the training design as agency staff worked together with their colleagues, as well as, staff from other agencies in role-play and feedback sessions. Both condition's training curricula utilized computer-based content including videos to provide modeling and the opportunity for review and scaffolded learning (F. & S., 2007; Noar, Black, & Pierce, 2009)

(Witte et al., 2014). Computer self-efficacy was assessed in the parent study as some ability to access computer-based resources would be required to utilize the training curriculum and video models, as well as, components of each intervention (e.g. the demonstration of videos modeling skills and HIV/STI informational video). Finally, maintenance, administrative and champion support, and supervision were reviewed in the training and followed up in the technical assistance calls to identify potential challenges and mechanisms to address them using internal resources and available outside technical assistance. lowering uncertainty about an innovation, efficiently done when knowledge is shared by those with greater experience with the innovation and through an organization's knowledge cross fertilization (Liu & Hart, 2011).

Table 3: Connect Implementation Strategy Components. Dose, and Mediators		
Strategy Core Component	**Mediator**	**Activity**
4-day in-class training 2 Technical Assistance Calls	Self-efficacy to implement Connect	• Identify the skills and characteristics needed to implement with couples • Identify previous experience to build on • Define and model core couples-based skills • Session content and scripts review guided by session goals and objectives • Orientation Session and Session One modeled by trainers; all other session core elements modeled • Staff practice conducting all sessions • Peer learning through observation and strength-based feedback and coaching from peers • Evaluation conducted post training to encourage participants reflection on confidence and readiness to implement • Enlist feedback on barriers and challenges to implementation encouraging self-appraisal • Review the role of practice in the agency setting • Provide on-going access to video models for review
4-day in-class training 2 Technical Assistance Calls	Perception of Intervention Characteristics	• Review the science behind the intervention's demonstrated efficacy • Discuss how a couples approach is unique and may fill agency service gaps for HIV prevention • Define resources and recommended budget needs • Identify ways the intervention may be tailored at the agency while maintaining fidelity • Facilitate agency-level discussions to plan for implementation and next steps addressing perceived barriers • Clarify target population for the intervention • Support adaptation • Review policies and procedures to support implementation and recruitment
4-day in-class training 2 Technical Assistance Calls	Champion	• Define the role of champion in pre- and post-training implementation • Agency staff brainstorm steps to engage leadership in intervention implementation • Enlist the identification of a champion or the steps to developing as an intervention champion

Quality assurance

All study procedures were recorded in a formal protocol during the study's Year 1. Following this protocol, the training sessions and two follow-up TA call adherence was measured by completion of a checklist of activities by study team staff (number, duration, and sequence of activities for each training session or TA call). TA calls followed a structured protocol with script implemented by at least two of the research team. The team debriefed following each call to confirm consistent topics had been addressed and action items planned and assigned to staff. Training content did not vary across trainings by more than 20% in terms of time, duration or sequence of activities for each session. TA assistance ranged in time and duration depending on the participants' responsiveness on the call. The call was planned for one hour, however, could vary by the number of staff participating, staff confidence, readiness, intention, stage of implementation and complexity of questions. Some themes that emerged during these implementation strategy 2- and 4-month "proactive" TA calls that may have impacted call times due to complexity were 1) correcting misunderstanding that Connect is not for HIV+ or serodiscordant couples, 2) integration of Connect into existing services and monitoring tasks to deduce redundancy, 3) Spanish language and same-sex and transgendered couple implementation, 4) adding Connect as a new service, incentives and funding opportunities, and 5) need for additional staffing and supervision.

Human Subjects Protection

Data from the Multimedia Connect Project was collected from 2008 through 2011, through funding from the National Institute of Mental Health, R01-MH080659, to Principal Investigator Dr. Susan Witte. Study procedures were approved by the Columbia University Institutional Review Board. The latest IRB renewal was received May 2015, and closure report in May 2016 with permission to analyze de-identified data. I have been closely involved on the project as co-investigator listed within the IRB protocol since inception. All identifiable information has been redacted from the dataset prior to analysis.

Data collection procedures

Measurements

Socio-Demographic Variables

The baseline survey questions addressed staff and organizational characteristics.

Staff Socio-demographic descriptive characteristics includes age, ethnicity, sexual orientation, education, years in HIV services at the agency, years in HIV services in the field, # of DEBIs trained on, whether DEBIs implemented, , and role as either an administrator or facilitator with the Connect project.

Organizational context includes descriptive indicators used for recruitment and paired randomization schema using # of staff in the organization, and # clients receiving multisession.

Independent measure

Implementation Strategy Exposure

Connect implementation strategy participation assessed the subjects' participation in a 4-day training and standard 2 follow-up technical assistance calls. The scoring is the summation of the number of days participating in the 4-day training plus the number of times participating in the two standard follow-up technical assistance calls. This variable ranges from 0 (never participate training and technical assistant calls) to 6 (participate all 4 days training and 2 standard technical assistance calls).

Outcome measure

Intention outcome (I) Connect implementation intention assessed the subjects' belief in their intention to implement Connect in the next six months. This is a single item variable "I plan to implement CONNECT in the next 6 months at my agency," scored with a 10-point Likert scale summed

for the overall score of this measure from 0-10, with "0" being "strongly disagree" to "10" "strongly agree."

Mediation Measurements

Individual Characteristics: Self-efficacy (SE) to implement Connect, a couples-based HIV/STI prevention intervention. Self-efficacy (SE) to implement Connect is measured by a single continuous variable: "I am able to successfully implement the Connect program/intervention" scored with a 10-point Likert scale summed for the overall score of this measure of 0-10, with "0" being "strongly disagree" to "10" "strongly agree."

Intervention Characteristics (IC): Favorable score on intervention attributes scale. Intervention characteristics measured with two measures: favorable attitude toward Connect using five intervention attributes from the Diffusion of Innovation (DOI) Theory and one item on cost of implementing Connect. The favorable attitude toward Connect intervention is constructed of five-single items assessing the following DOI attributes: "Including Connect in our prevention programming improves our ability to reduce risk among heterosexual couples" (Relative advantage); "Connect is a program that fits (or blends) well with the culture, needs, other services as well as the mission of our organization (Compatibility); "Connect is easy to understand and easy to conduct" (Complexity); "I have the time and opportunity to conduct Connect for practice first before I actually work directly with clients on it" (Trialability) and "I see the contributions that Connect makes with our clients" (Observability) with a scale of 10-point Likert scales summed for the overall score of this measure. The reliability for the favorable attitude scale is Cronbach's alpha .81. A factor analysis found the five items loading on one factor.

We explored a single item measure of perception of cost to implement the intervention Connect to see its relationship to outcome intention and its relation to factors in the mediator IC scale for potential inclusion in this measure: "The cost of conducting Connect prevents the agency from implementing Connect" using a 10-point Likert scale summed for the overall score of this measure and found significant

association with intervention characteristic score. The perception of staff that the cost of conducting Connect prevents the agency from implementing Connect at baseline was significantly and negatively associated with intention to implement in the next six months at baseline (p=0.001) yet the significant association was lost at six months (p=0.3) and 12 months (p=0.5) (See Appendix C). It did not, however, add an additional loading factor for the IC scale and, therefore, was not included in the IC measure.

Organizational Process Level: Champion (C)

This mediator variable belief that an intervention champion was available in the organization was measured by a single dichotomous measure No=0 and Yes=1: "Would you say that your current agency has a 'champion' for Connect?" (As defined in the survey: "A champion could be you and/or someone who believes so strongly in the usefulness of a program that they will work with staff to find solutions to implement the program.")

Control Variables Measurement

Gender: is a bivariate variable measured Male =0 and Female = 1

Age: re-coded as a categorical variable 18-29, 30-39, 40 and above.

Education: measured with one question "What is the highest grade completed in your educational experience?" coded as high school, college or graduate school.

Race/ethnicity: measured with one question: "Which of the following races or ethnicities best describes you?" coded as Black, Latino, White or other."

Tenure in HIV field: measured by one question "How many years have you been employed in the field of HIV". Length of time in the field was found to be positively associated with implementing DEBIs. To reduce potential noise introduced by previous experience and to more accurately examine the

association of the implementation strategy dosage and Intention to implement and to the three chosen mediators I controlled for this variable.

Tenure at the agency: recoded into categories-- less than 2 years, 2-5 years, 6-10 years and more than 10 years.

Condition assignment: measured by randomized condition assignment coded Multimedia =0 and Traditional =1.

Baseline intention score: Measured by a single item variable "I plan to implement Connect in the next 6 months at my agency," scored with a 10-point Likert scale summed for the overall score of this measure from 0-10, with "0" being "strongly disagree" to "10" "strongly agree."

Role with Connect: coded as administrator =0 or facilitator= 1. Each agency was asked to designate one administrator for their agency cohort.

DEBIs facilitated: (DEBI is an evidence-based HIV prevention intervention chosen by the CDC as a best evidenced intervention and is being diffused by the CDC and its capacity building branch): Bivariate variable either did not facilitated =0 or did not =1. Previous experience in EBI implementation is believed to increase the likelihood of intent to implement Connect.

Specific AIMs and Hypothesis

Guided by the CFIR and prior literature and research on implementation, behavior change, capacity building and by the parent study findings and protocols, this dissertation tested the following AIMS and hypotheses:

Inner Setting

Individual staff characteristics

AIM 1:

To examine the effect of the Implementation Strategy for the Connect, couples-based HIV/STI prevention intervention (independent variable) at 6- and 12-months (participation in a 4-day training and standard 2 follow-up technical assistance calls) on the intent to implement (dependent variable) the intervention with their clients among a sample of 253 staff working in HIV prevention and services among 80 organizations in New York State.

H_1: Participants who received higher number of days of the Connect implementation strategy (4-day training and 2 follow-up technical assistance calls) than their counterparts are likely to have greater intention to implement Connect in the next six months at 6 and 12 months follow-up controlling for condition, age, gender, ethnicity, education and number of years in HIV service, role in agency regarding Connect (administrator or facilitator), baseline Intention to implement and facilitated DEBIs.

AIM 2: To examine whether self-efficacy mediates the Effect of the Connect implementation strategy (independent variable) at 6- and 12-months on the intent to use the intervention with their clients (dependent variable) in the next six months with a sample of 253 staff working in HIV prevention and services among 80 organizations in New York State.

H_2: Participants with higher reported self-efficacy to implement Connect mediates the effect of more days of attendance of the Connect implementation strategy (4-day training and 2 follow-up technical assistance calls) and their intention to implement Connect, couples-based HIV/STI prevention with their clients in the next six months at 6- and 12-months follow-up.

Intervention Characteristics

AIM 3: To examine whether a favorable perception of the Connect intervention mediates the effect of the Connect implementation strategy at 6- and 12-months (participation in a 4-day training and standard 2 follow-up technical assistance calls) on the intent to use the intervention with their clients (dependent variable) in the next six months with a sample of 253 staff working in HIV prevention and services among 80 organizations in New York State.

H_3: Participants with more favorable perception scores of the Connect intervention compared to those with lower scores mediates the effect of more days of attendance of the Connect implementation strategy (4-day training and 2 follow-up technical assistance calls) and their intention to implement Connect, couples-based HIV/STI prevention with their clients in the next six months at 6- and 12-months follow-up.

Inner Setting

Organizational factor

Process

AIM 4: To examine whether staff belief in the availability of an intervention champion mediates the effect of the Connect implementation strategy (independent variable) at 6- and 12-months (participation in a 4-day training and standard 2 follow-up technical assistance calls) on intention to use the intervention with their clients (dependent variable) in the next six months with a sample of 253 staff working in HIV prevention and services among 80 organizations in New York State.

H_4: Participant's belief in the availability of an intervention champion mediates the effect of more days of attendance of the Connect implementation strategy (4-day training and 2 follow-up technical assistance calls) and their intention to implement Connect, couples-based HIV/STI prevention with their clients in the next six months at 6- and 12-month follow-up.

Data Analysis

Exploratory Analysis.

In general, a variety of statistical methods have been employed for the purpose of exploratory analysis. Descriptive analyses were used to describe the sample frequencies and distributions of variables of interest included. To detect outliers, standard methods of analysis of leverage statistics were used for the primary variables. Tests of association were conducted using analysis of variance, and correlations procedures to identify unadjusted associations among predictor, mediators and the outcome variable. Multicollinearity was not found among the chosen control variables (See Appendix 1, Table 2). Model assumptions were assessed using appropriate regression diagnostics and model fit statistics and multiple imputation (described below) was included to adjust for skewed and missing data. Selection of variables of interest was based on theoretical and previous study considerations as well as the exploratory examination of data as described above. This is a practical approach that incorporates additional information from prior research, including randomized experimental studies, theory, and qualitative methods to strengthen the initial conclusion that a mediation relation exists. Researchers often test whether there is complete or partial mediation by testing whether the c ′ coefficient is statistically significant, which is a test of whether the association between the independent and dependent variable is completely accounted for by the mediator. Because psychological constructs, such as self-efficacy or intentionality, have a variety of causes, it is often unrealistic to expect that a single mediator would be explained completely by an independent variable to dependent variable relation (Judd, Kenny, & McClelland, 2001) we will interpret the findings cautiously considering the contextual considerations All statistical analyses performed was conducted with SPSS 20.0 and SAS 9.4 software packages.

Statistical Power.

The statistical power available to detect effect sizes is estimated based on a general, although less robust, method of estimation. For regression analyses, Green (Green, 1991) suggests n > 50 + 8*p (where p is the number of predictors)c for testing the multiple correlation. With a sample of n=253, it was determined that there should be sufficient power to include up to 25 predictors (50+8*p=50+8*25=250) with a medium-sized relationship. Smaller relationships could be detected with fewer covariates in the models chosen.

Direct Effect on Outcome and Mediation analysis procedures

The purpose of the analysis was to test the hypotheses reported above on whether the independent variable directly effects the dependent variable in hypothesis 1 and described in Step 1 below, and whether variables described in hypotheses 2-4 potentially mediate the relationship between the implementation strategy dose and the primary study outcome, intention, of this dissertation. Three mediators (self-efficacy, intervention characteristics, and availability of a champion) were examined on the primary study outcome of intention to implement in the next 6 months at two follow-up time points, 6 and 12 months. To test the mediation effects with a field in flux as new methods are designed, I conducted four analytic steps by adopting the more traditional analytic approach from Baron and Kenny (Baron & Kenny, 1986) for this inquiry. Because the data are longitudinal and the unit of analysis is individual staff nested within groups, I considered the appropriateness of a multilevel model versus multiple linear regression with multiple imputation to address missing data.

Multiple Regression

I considered a multilevel regression model to take into account the intraclass correlation (ICC) (Krull & MacKinnon, 2001) due to nested data of individual staff members within an agency cohort and the repeated measures at follow-up two time points. However, Muthen and Satorra (Muthen & Satorra, 1995) suggest that with a design effect > 2 you would need to account for clustering by adopting a

multilevel model. To test for the need for a multilevel model the design effect calculation = 1 + (average cluster size - 1)*intraclass correlation. For this study data at 6 months, this is 1 + (2.53 – 1)*0.26 = 1.40, which suggested I could ignore the clustering effect and conduct a linear regression.

Additionally, I considered the temporal effect of mediators at 6 and 12 months distinctively and used the baseline outcome variable (Intent to implement Connect) as a covariate. This strengthens the model to control for the baseline score to focus on mediator effects. In this dissertation the unit of analysis is the individual staff that was a member of an organization attending a Connect implementation strategy which included a group training and collective technical assistance call with individual organizations.

Multiple Imputation Technique

100% of the 253 staff completed the baseline survey with follow-up rates at 91% and 88% for 6 and 12 months respectively. These follow-up rates exceeded the 80% rate widely accepted as an acceptable for RCTs. I used multiple imputation (MI) (Cummings, 2013; Schafer, 1999) to reduce or correct for potential bias introduced by missing data caused by lost to follow-up participants. The MI procedure is used to obtain desirable estimates at the first of three analytic steps in order to adjust for potential bias due to missing data; and to obtain the standard errors for the products of the coefficients at the last analytic step in order to test the significance of the direct and mediation effects. MI uses a participant's observed or measured information to predict values of variables for which that individual's information is missing. MI relies on more plausible assumptions than do ad hoc imputation methods such as complete case analysis, missing value treated as failure, or last observation carried forward. Moreover, because MI replaces each missing value with several imputed values, it can account for uncertainty about the missing values better than single imputation and yield appropriate standard errors for the effect estimates. MI is a Monte Carlo technique in which the missing values are replaced by m > 1 simulated versions, where m is typically small (say, 3±10). In this case I used K=37 case imputations. It was

assumed that data were missing at random (MAR) as staff turnover, a common challenge for EBI implementation in community-based organizations, is likely responsible for some missingness.

AIM 1 Direct Effect of Implementation Strategy Dosage on Outcome

Step 1: Estimate implementation strategy's effect on study outcome

The first step I conducted was examining implementation strategy exposure direct effect (4-day training and 2 technical assistance [TA] follow-up calls) on the primary study outcome at the 6-month and 12-month follow-ups (see Table 6, Figure 2). The effect size was estimated by regressing the intention outcome variable on implementation strategy participation as defined by the number of days (0-6) of participation in the intervention. Also in the regression model, the baseline measurement education and number of years in HIV services was included as covariates. Number of years in HIV services was included to take into account the likely experience of self-efficacy that may be associated with additional exposure to evidence-based intervention implementation. Additionally, the mean score on baseline intention to implement was included as a covariate to reduce noise in the examination of post implementation strategy effect on the outcome and mediating variables. The random-effect estimate, which I employed in this study, addresses the major portion of group effect. The estimate equation for this step is:

$$Intention = \boldsymbol{C}_0 + \boldsymbol{C}_1 \times dosage + \boldsymbol{C}_2 \times condition + \sum \boldsymbol{C}_j \times f(sociodemographics)_j + \mathcal{E}_1$$

Where *intention* denotes intention to implement in the next 6 months; $\boldsymbol{C}_1 \times dosage$ denotes intervention participation; *condition* refers to the random assignment to either the multimedia and traditional method of couple-based intervention*; f(sociodemographics)= f(age, gender, ethnicity, education and number of years in HIV service, role in agency, score on baseline intention and experience of facilitating DEBI);* and *j=3-10.*

The coefficient C_1 provides the effect size of intervention dosage on the intention at each follow up, six and 12 months. If the intervention effects are found significant in this step, then testing the relationship between intervention dosage effect and mediators would be meaningful in the next step. In this case statistical significance was found and is reported in the results section.

AIM 2-4 Mediation Analysis

Step 2: Estimate intervention effects on mediator

The second step is to determine whether the intervention improved the mediator or demonstrates that the causal variable is correlated with the mediator. I used M as the criterion variable in the regression equation and X as a predictor (estimate and test path a). This step essentially involves treating the mediator as if it were an outcome variable.

The estimate equation for this step is:

$$Mediator_{t3} = a_0 + a_1 \times dosage + \varepsilon_2$$

Where *mediator* denotes one of the three mediators included in AIMs2-4 in this study: 1) Connect implementation self-efficacy; 2) perception of Intervention Characteristics score and the 3) perception of the availability of a Connect champion in the organization. The coefficients a_1 provide the effect size of the dosage effect on the mediator of interest.

Step 3: Estimate intervention and mediation effects on study outcomes

The third step is to estimate simultaneously two kinds of effects, intervention dosage and mediation, on primary study outcome. The estimate equation is:

$$Intention = C_0 + C_1 \times dosage + C_2 \times condition + b \times mediator + \sum C_j \times f(sociodemographics)_j + \varepsilon_3$$

The coefficients C'_1 provide the intervention dosage effects at each follow-up after taking mediation

effects into account. The coefficient provides the effect size of the mediator of interest on the study outcome at each follow-up 6-month and 12-month follow-up, respectively.

Step 4: The final step is to evaluate whether the mediation effects were presenting with the intervention effect by drawing conclusions from the first three steps. This is establishing that if M completely mediates the X-Y relationship, the effect of X on Y controlling for M (path c') should be zero. If the significant effect of X on Y is reduced when the mediator is introduced then this is considered partial mediation. In this case, partial mediation means that the parameter estimate for implementation strategy dose shrinks when the mediator is added, but does not disappear or become zero. Complete mediation occurs if it goes to 0 (or so close as it makes no difference).

Chapter IV:

RESULTS

Results

Sample socio demographic variables: staff

The study sample (see Table 4) includes 253 staff participants (131 web-based method assignment and 122 traditional method assignment) across the 80 agencies, with an average of 3 per agency (range 1-6). Most were female (71.5%), mean of 42 (range 22-66) years of age, heterosexual (83%) and single, African American (41%) and with an education beyond high school (80%) with 35 MSW and 2 PhDs. Participants had an average of 7 years of experience in HIV services and 3 years as this current agency, and reported an average of 9 out of 10 in relative confidence in computer use and in using an Internet browser. One hundred and ten or 43.5 % reported being trained in a DEBI. Sixty-seven (26.5%) have facilitated a DEBI with a mean of 2, and reported at baseline having the skills needed to facilitate effectively with couples with a mean score of 3.91 (1-5). 65 (35%) reported the perception of having an intervention Champion at baseline. We found a statistically significant positive association with the staff attitude toward DEBIs and their implementation of at least 1 DEBI (p=0.002). Age was positively associated with having been trained in at least one DEBI (p=-0.05).

Unequal distribution of baseline characteristics among the two condition groups was examined through tests of overall association and through comparisons of specific group contrasts used in the analyses. For these analyses, the chi-square statistic was used for categorical variables, and the t-test for independent samples was used for continuous variables. Critical to this study we found no significant differences regarding condition assignment and socio demographic variables at baseline. Level of education was not significantly associated with group assignment, with the TRAD group having 49% with college level of education than the MM group with 40%, while the MM group had 41% with

graduate degrees in comparison to 38% in TRAD. No significant group differences were found at baseline for number of years in HIV prevention in general nor years in HIV prevention at their agency. This supported the appropriateness of the combined sample for this study's aims.

A T-test did find a statistically significant ($P<0.05$) association with staff implementation of DEBIs and YRS in HIV Service. Years in service was then controlled in this study to reduce the potential bias of prior experience on intention to more accurately interpret the dosage effect of this implementation strategy.

Table 4. Sample Sociodemographic Characteristics for Staff and Reported Previous EBI† facilitation

	Total sample (n=253)		**Facilitated EBIs** (n=67)	
Sociodemographic	*N*	*Percentage*	*N*	*Percentage*
Sex				
Female	181	71.5	47	70.1
Male	72	28.2	20	29.9
Age				
18-29	40	15.8	6	9
30-39	66	26.1	19	28.4
40 and above	147	58.1*	42	62.7
Marital Status				
Married	81	32.0	21	31.0
Separated, Divorced, Widowed	56	22.2	21	31.7
Single	116	45.8	25	37.3
Sexual Orientation				
Heterosexual	209	82.6	51	76.1
Gay	22	8.7	9	13.4
Lesbian	12	4.7	4	6.0
Bisexual	8	3.2	3	4.5
Other	2	.8	0	0
Race-Ethnicity				
African American	104	41.1	40	59.7*
Hispanic	92	36.4	23	34.3
Caucasian	55	21.7	6	9.0
Caribbean, West Indian	19	7.5	6	9.0

Asia, SE Asia, Pac Islander.	10	4	3	4.5
Preferred language				
English	221	87.4	57	85.1
Spanish	21	8.3	6	9.0
Other, Chinese, French	11	4.4	4	6.0
Education				
High School or GED	40	15.8	16	23.9
College or Technical school	113	44.70	31	46.3
Graduate school	100	39.5	20	29.9

	Did not facilitate EBIs (N=185)		*Facilitated EBIs (n=67)*	
	Mean	*Range*	*Mean*	*Range*
Age	41.8	22-66	42.5	23-63
Yrs in HIV/STI services	3.5	0.5-15	4.24 ***	0.5-15
Yrs in service at this agency	2.9	1-5		

** Indicates x^2 tests of independence indicates a statistically significant ($p<0.05$) association with their facilitation of at least one EBI.*

*** x^2 tests of independence indicates a statistically significant ($P<0.05$) association with their being trained in at least one EBI.*

**** A T-test demonstrated a statistically significant ($P<0.001$) association with their facilitation of at least one EBI.*

†EBIs here represents HIV prevention interventions chosen as best evidence by the CDC, formerly called DEBIs.

Sample descriptive variables: organizations

Table 5. Characteristics of HIV Service Agencies (N=80) and those offering EBIs**

	Does not offer EBIs (n=22)			Offers EBIs (n=58)			All agencies (N=80)	
	Mean	**Median**	**Range**	**Mean**	**Median**	**Range**	**Median**	**Range**
HIV/STI prevention budget	$1, 884,181	$100,000	0 to $35M	$759,669	$451,000	$0 to $4M	$362,000	0 to $35M
Full-time HIV prevention staff	19.6	6	0-216	17†	10	1-147	17.9	0-216
Part-time HIV prevention staff	3.32	1.5	0-20	2.4	1.0	0-20	2.6	0-20
No. clients receiving HIV prevention services	4,653	1,487.5	20-40,000	5,579	1,192	50-81,500	1,200	0-81,500
No. clients receiving *multi-session* HIV prevention srvces	243.1	27.5	0-1,500	607.7‡	125.5	0-8,000	102.5	0-8,000
% of heterosexual clients	63	78	9-90	77.5	85	25-96	80	9-96
Yrs of participating staff employment at agency	2.72	3.0	0-13	3.0	3.0	0-13	5.43	0-13[1]
# EBIs offered*				2.4	3	0-7		0-23

***EBIs here represents HIV prevention interventions chosen as best evidence by the CDC, formerly called DEBIs.*

**21 distinct EBIs offered out of 23 listed in the baseline survey. Additional EBIs have been added during follow up surveys.*

[1] Categorical data

† A T-test demonstrated a statistically significant (P<0.06) association between organizational characteristic and their facilitation of at least one EBI.

‡A T-test demonstrated a statistically significant (P<0.06) association between organizational characteristic and the agency offering of at least one EBI.

Organizational characteristics (see Table 6) of the 80 participating agencies by evidence-based interventions offered (EBIs) included a median HIV/STI prevention budget of $362,000 per year and median number of fulltime prevention staff between 8 and 9. Agencies served a median of 1200 clients

each year, with a median of 102 clients receiving multi-session, HIV prevention services. 59% of the organizations stated they were implementing DEBIs with an average of 2.4 intervention programs serving 80% heterosexual clients. Despite variability, there were no significant differences on organizational characteristics at baseline by condition, suggesting that the matched pairs approach for randomization yielded relatively balanced groups for the trial (Witte et al., 2014). Six agencies (2.75%) reported receiving funding to conduct Connect at baseline. The comparable nature of the paired 80 organizations by condition in the parent study supported the examination of a pooled sample in this study.

Implementation Strategy Exposure [4 day training and 2 technical assistance calls (0-6).]

Ninety-nine staff (39%) of the sample reported attending all 6 contacts of the implementation strategy while 8 (3%) reported no attendance. Forty-five (18%) reported attending only the 4-day training (See Table 6 below).

Table 6. Training and TA Attendance Dosage (N=253)

Days/contacts (0-6)	Frequency	Percentage
0	8	3.16
1	15	5.93
2	24	9.49
3	5	1.98
4	45	17.79
5	57	22.53
6	99	39.13
Total	253	100.00

Primary Outcome Variable: Intention to Implement in the Next Six Months (Baseline)

Staff report of intention to implement in the next six months at the six month follow-up (See Table 7) was normally distributed with 15 (8.4%) reporting no intent, 72 (40%) reporting moderate intention and 22 (12%) reporting full intent to implement. Of note, baseline intention to implement was significantly associated with intention at 12 month (p=0.006) but not at six months (p=0.3) (See Appendix B). College education (p=<0.0001) and graduate school (p=0.003) were associated with intention to implement in the next six months.

Table 7. Intention to implement Connect in six months (N=178) (6 month follow-up)

Range (0-10)	Frequency	Percentage
0	15	8.43
1	8	4.49
2	9	5.06
3	5	2.81
4	3	1.69
5	72	40.45
6	7	3.93
7	5	2.81
8	14	7.87
9	18	10.11
10	22	12.36
Total	178	100.00

Control variables

A test of Variance Inflation Factor (VIF)(O'brien, 2007) was conducted to assess the degree of multi-collinearity of the independent variables selected for the regression models (See Appendix A). No collinearity was found as the VIF was <2 and we determined the variables would contribute to the model as controls to reduce confounding.

AIM 1 and Direct effect hypothesis

Step 1: Estimate implementation strategy exposure effects on study outcome

For the first step in the analysis I examined the direct effect of the implementation strategy dosage on the outcome to determine whether there was a statistically significant effect of the implementation strategy on the outcome to ensure that mediation analysis was appropriate to conduct in this study. Tables 8 and 9 present the regression results of the outcome of intention to implement in the next six months at 6 and 12-months, respectively, by intervention exposure described in Step 1 of the analytic plan. With respect to the relationship between the number of days of intervention (dosage) participation (0-6), the effect size at follow-up demonstrated a statistically significant association among those with greater intervention dosage (more days of participation 0-6) and higher scores of intention to implement Connect, couples-based HIV/STI prevention within 6 months at the 6 months follow-up (0.4, p= 0.03, SE 0.19 [0.3, 0.77])* (See Table 7, Figure 2) and a small effect size yet not significant at 12 months follow-up (0.25, p= 0.11, SE 0.16 [-0.06, 0.55]) (See Table 8, Figure 3). The significance of implementation strategy dosage direct effect on study outcome of intention to implement at 6- months gives evidence to reject the null hypothesis and supported continuation to the next step of analysis for the mediator effect on the dose of implementation strategy and outcome for AIMs 2-4. Examining the implications of the loss of significant effect at 12 months of the implementation strategy dosage on intention is an important contribution of this study. The loss of the significant effect at 12 months highlights the import temporal effect on intention to implement post implementation strategy for decision-making and for the

consideration of on-going strategies to support and sustain any momentum begun toward implementation beyond this period.

Table 8 AIM 1 Results Direct Effect Implementation Strategy on Intention at 6 months

Variable	Model at 6 months		
	Parameter estimate	Standard error	95% CI
Intercept	4.41**	1.54	1.37-7.44
Training	0.40*	0.19	0.03-0.78
Intention to implement			

Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment

* p < 0.05

** p < 0.01

*** p < 0.001

Figure 2

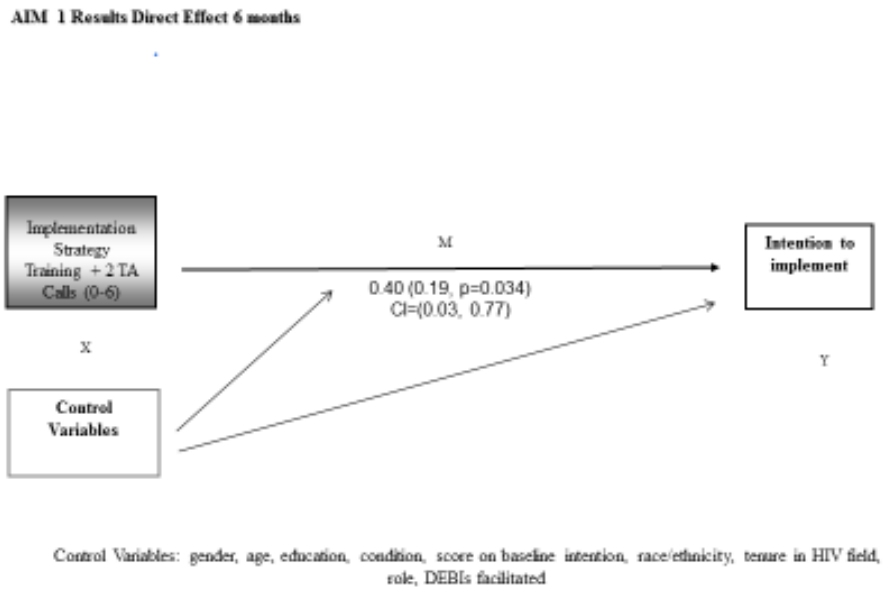


Table 9 AIM 1 Results Direct Effect Implementation Strategy on Intention at 12 months

Variable	Model at 12 months		
	Parameter estimate	Standard error	95% CI
Intercept	4.41**	1.54	1.36-7.44
Training	0.25*	0.16	0.06-0.55
Intention to implement			

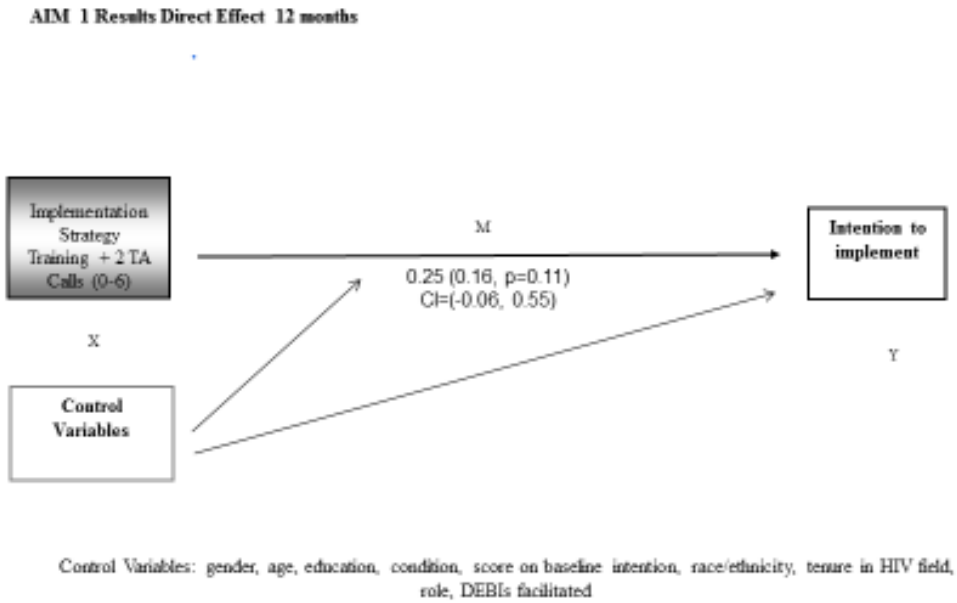
Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment

* p < 0.05

** p < 0.01

*** p < 0.001

Figure 3



AIM 2 and mediation hypothesis

As noted in methods, mediation analysis involves four steps:

1. Estimating implementation strategy dosage effects on study outcome
2. Estimating implementation strategy dosage effects on mediator
3. Estimating implementation strategy dosage and mediation effects on outcome
4. Evaluating the above

Aim 2 involved examining the mediation effects of self-efficacy on the relationships between the dose of implementation strategy and intent to use the program. For the first step, at six months, we found a positive association and significant effect between the dose of implementation strategy and intent: (β = 0.34, SE = 0.19, df = 120.07, p = 0.03, 95% CI = 0.10 to 0.77). For the second step, non-significant relationship between the dose of implementation strategy and the mediator: β = 0.34, SE = 0.22, df = 317.51, p < 0.13, 95% CI = 0.10 to 0.78) (See Table 10, Figure 4). For the third step, significant relationship between the mediator and the outcome variable intent: β = 0.43, SE = 0.06, df = 317.51, p < 0.01, 95% CI = 0.31 to 0.56) (See Table 10, Figure 4).For the fourth step, we evaluate when the mediator was added to the model, the relationship between implementation strategy and intent was reduced and no longer statistically significant: β = 0.43, SE = 0.06, df = 118.2, p = 0.01, 95% CI = -0.31 to 0.56). Without detection of a significant relationship between the implementation strategy dosage and the mediator we cannot conclude a mediating effect. We may not have been powered sufficiently to capture this relationship. While we do not know how the dosage impacted self-efficacy directly it is important to recognize the strong relationship between self-efficacy and intention to implement. Additionally, while these findings do not explain the variation of dosage on intention, they confirm self-efficacy as an important factor to consider in implementation strategies promoting intention to utilize this innovation. Another measurement or scale for this implementation strategy rather than dosage may better inform any mediating relationship between the strategy and intention to implement in the next six months.

Table 10 Mediation analysis for Aim 2: Self-efficacy at 6 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.41**	1.54	1.37-7.44	1.47	1.42	-1.33 – 4.28
Training	0.40*	0.19	0.03-0.78	0.18	0.18	-0.17-0.53
Self-Efficacy				0.44***	0.06	0.31-0.56

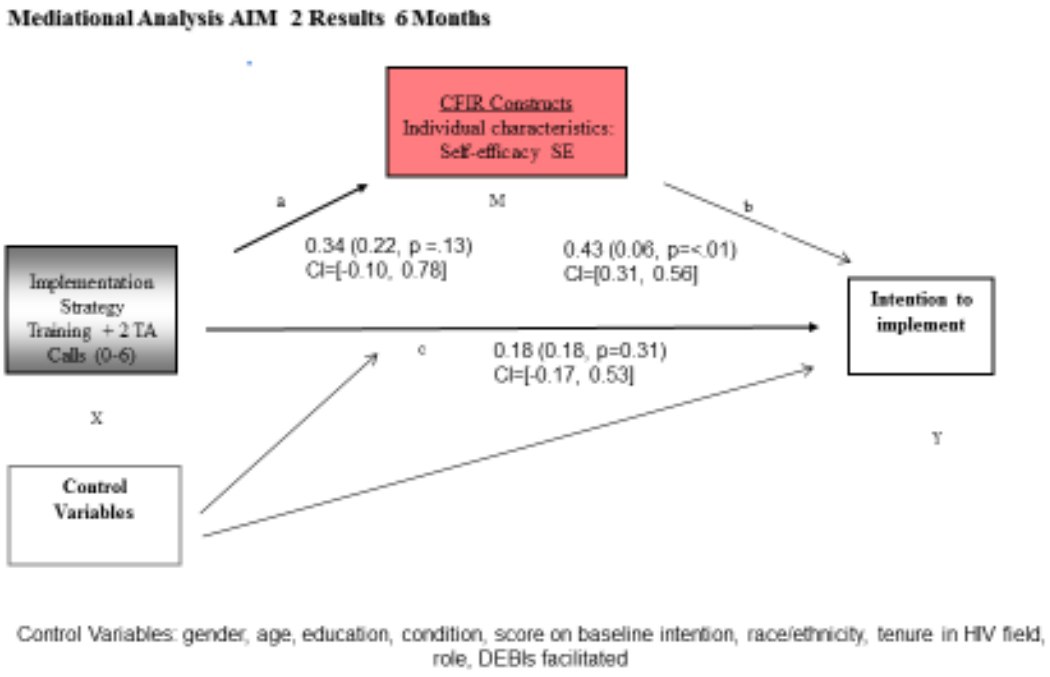
Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment

* $p < 0.05$

** $p < 0.01$

*** $p < 0.001$

Figure 4



For the first step, at 12 months, we did not find a significant effect between the dose of implementation strategy and intent: ($\beta = 0.18$, SE = 0.18, df = 114.27, $p = 0.31$, 95% CI = -0.17-0.53). For the second step, non-significant relationship between the dose of implementation strategy and the

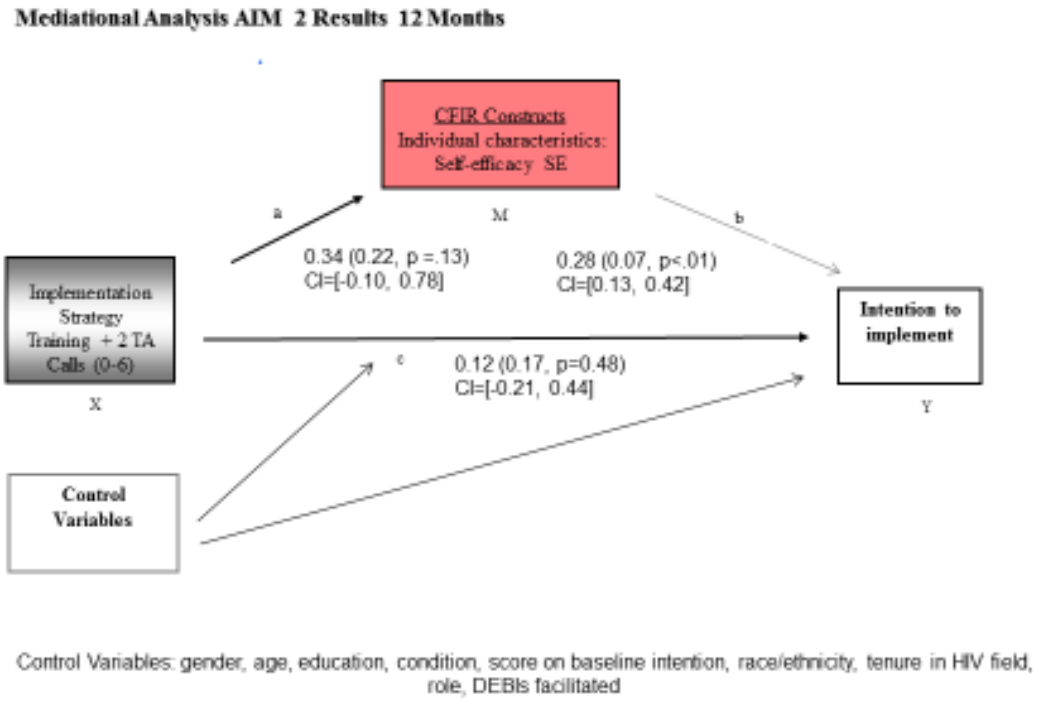
mediator: β = 0.34, SE = 0.22, df = 317.51, p < 0.13, 95% CI = 0.10 to 0.78) (See Table 11, Figure 5). For the third step, there was a significant relationship between the mediator and the outcome variable intent: β = 0.28, SE = 0.07, df = 317.51, p < 0.01, 95% CI = 0.13 to 0.42) (See Table 11, Figure 5). For the fourth step, we evaluate when the mediator self-efficacy was added to the model, the relationship between the dose of implementation strategy and intent was reduced: β = 0.12, SE = 0.17, df = 345.66, p = 0.48, 95% CI = -0.21 to 0.44). Without the statistically significant relationship between the implementation strategy dosage and the outcome at 12 month intention to implement nor in the relationship with the mediator self-efficacy, we do not find a full or partial mediating effect of self-efficacy for the dose of implementation strategy (See Table 11, Figure 5).

Table 11 Mediation analysis for Aim 2: Self-efficacy at 12 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.19**	1.51	1.22-7.15	1.09	1.48	-1.81 – 4.00
Training	0.25	0.16	-0.06-0.56	0.12	0.17	-0.21-0.44
Self-Efficacy				0.28***	0.07	0.13-0.42

Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment
* p < 0.05
** p < 0.01
*** p < 0.001

Figure 5



AIM 3 and mediation hypothesis

Aim 3 involved examining the mediation effects of favorable perception of the Connect couples-based intervention on the relationships between the dose of implementation strategy and intent to use the program. For the first step, at six months, we found a positive association and significant effect between the dose of implementation strategy and intent: ($\beta = 0.40$, SE = 0.19, df = 120.07, $p = 0.03$, 95% CI = 0.03 to 0.77) (See Table 12, Figure 6). For the second, there was a non-significant relationship between the dose of implementation strategy and the mediator: $\beta = 0.20$, SE = 0.02, df = 75.59, $p = 0.01$, 95% CI =-1.09-1.56. For the third step, there was a significant relationship between the mediator and the outcome variable intent: $\beta = 0.20$, SE = 0.02, df = 317.51, $p < 0.01$, 95% CI = 0.17 to 0.24) (See Table 12, Figure

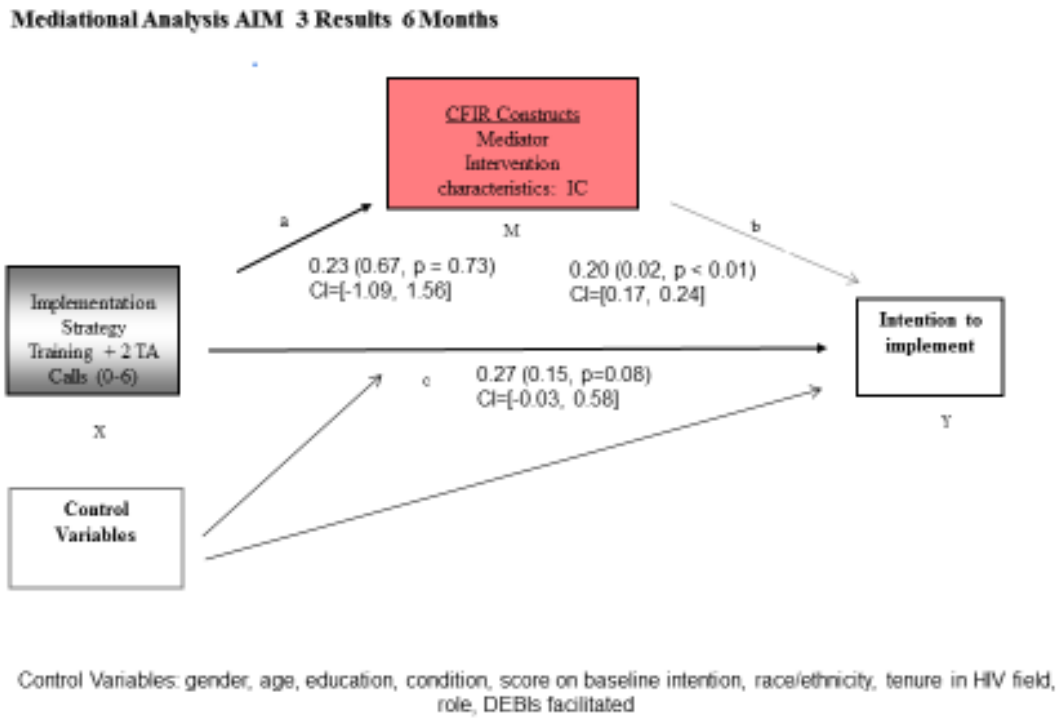
6). For the fourth step, we evaluate when the mediator was added to the model, the relationship between the dose of implementation strategy and intent was reduced and marginally significant: β = 0.27, SE = 0.15, df = 217.35, p = 0.08, 95% CI = -0.03 to 0.58) (See Table 12, Figure 6). Without a significant relationship between the implementation strategy dosage and the mediator favorable perception of the Connect couples-based intervention at six months, we cannot report a full or partial mediating effect of positive perception of intervention characteristics for the dosage of the implementation strategy. This is an important finding to note the favorable perception of the Connect couples-based intervention was not directly impacted by the dose of implementation strategy. However, the b pathway demonstrated a significant relationship between the mediator and the outcome (p=<.01). While these findings do not explain the variation of dosage on intention, they suggest favorable perception of the Connect couples-based intervention as an important factor to consider in implementation strategies promoting intention to utilize this innovation. Another measurement of this implementation strategy rather than dosage may better inform the mediating relationship between the strategy and intention to implement in the next six months.

Table 12 Mediation analysis for Aim 3: Intervention Characteristics at 6 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.41**	1.54	1.36-7.44	-0.41	1.25	-2.88-2.06
Training	0.40*	0.19	0.03-0.78	0.27	0.15	-0.03-0,58
Intervention characteristics				0.20***	0.02	0.17-0.24

Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment
* p < 0.05**, p < 0.01, *** p < 0.001

Figure 6



For the first step, at 12 months, we did not find a significant effect between the dose of implementation strategy and intent: (β = 0.18, SE = 0.18, df = 114.27, p = 0.31, 95% CI = -0.17-0.53). For the second, there was non-significant relationship between the implementation strategy and the mediator Intervention characteristic: β = 0.23, SE = 0.67, df = 75.59, p = 0.73, 95% CI =-1.09-1.56. For the third step, there was a significant relationship between the mediator and the outcome variable intent: β = 0.14, SE = 0.02, df = 317.51, p < 0.001, 95% CI = 0.09 to 0.19) (See Table 13, Figure 7). For the fourth step, we evaluate when the mediator was added to the model, the relationship between the dose of implementation strategy and intention to implement and found a reduction in the p-value: β = 0.17, SE = 0.17, df = 194.62, p = 0.31, 95% CI = -0.16 to 0.50). Without the statistically significant relationship

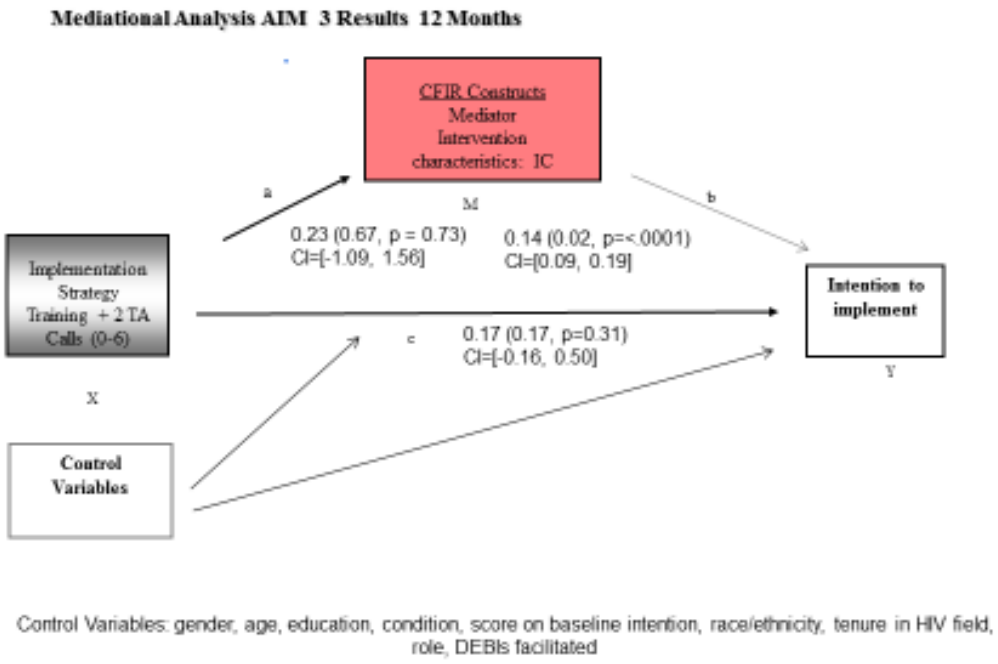
between the implementation strategy dosage and the outcome at 12 month intention to implement nor in the relationship with the mediator positive perception of intervention characteristics, we do not find a full or partial mediating effect of a positive perception of intervention characteristics on the dose of implementation strategy (See Table 13, Figure 7). The findings do confirm the importance of the perception of an intervention Champion on intention to implement (p=<0.001) and further examination is needed in order to understand how the implementation strategy impacts this important mediator toward implementation.

Table 13 Mediation analysis for Aim 3: Intervention Characteristics at 12 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.18**	1.51	1.22-7.16	1.48	1.47	-1.40-4.35
Training	0.25	0.16	-0.06-0.56	0.17	0.17	-0.16-0.50
Intervention characteristics				0.14***	0.02	0.09-0.19

Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment
* p < 0.05
** p < 0.01
*** p < 0.001

Figure 7



AIM 4 and mediation hypothesis

Aim 4 involved examining the mediation effects of perception of the availability of an intervention Champion of the Connect couples-based intervention on the relationships between the dose of implementation strategy and intent to use the program. For the first step, at six months, we found a positive association and significant effect between the dose of implementation strategy and intent: (β = 0.40, SE = 0.19, df = 120.07, p = 0.03, 95% CI = 0.03 to 0.77). For the second, there was a non-significant relationship between the dose of implementation strategy and the mediator staff perception of availability of an intervention Champion within the organization: β = 0.002, SE = 0.02, df = 1322.1, p = 0.90, 95% CI = -0.04 to 0.04). For the third step, there was a significant relationship between the

mediator and the outcome variable intent: β = 2.13, SE = 0.43, df = 317.51, p < 0.01, 95% CI = 1.27 to 2.98) (See Table 13, Figure 7). For the fourth step, we evaluate when the mediator was added to the model, the relationship between the dose of implementation strategy and intent was reduced and no longer significant: β = 0.33, SE = 0.18, df = 116.28, p = 0.07, 95% CI = -0.03 to 0.69). Without a significant relationship between the implementation strategy dosage and the mediator perception of the availability of an intervention Champion of the Connect couples-based intervention at six months, we cannot report a full or partial mediating effect of staff perception of an intervention Champion within the organization on the dose of implementation strategy (See Table 14, Figure 8). This is an important finding to note the perception of a Champion was not directly impacted by the dose of implementation strategy. However, the b pathway demonstrated a significant relationship between the mediator and the outcome (p=<.01) and highlights the important relationship between the perception of the availability of an intervention champion and intention to implement. Further measurement of this factor in relationship to the implementation strategy of training and technical assistance is needed to capture effect.

Table 14 Mediation analysis for Aim 4: Intervention Champion at 6 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.41**	1.54	1.36-7.44	3.25	1.42	0.47-6.03
Training	0.40*	0.19	0.03-0.78	0.33	0.18	-.0.03-0.69
Champion				2.12***	0.43	1.27-2,97

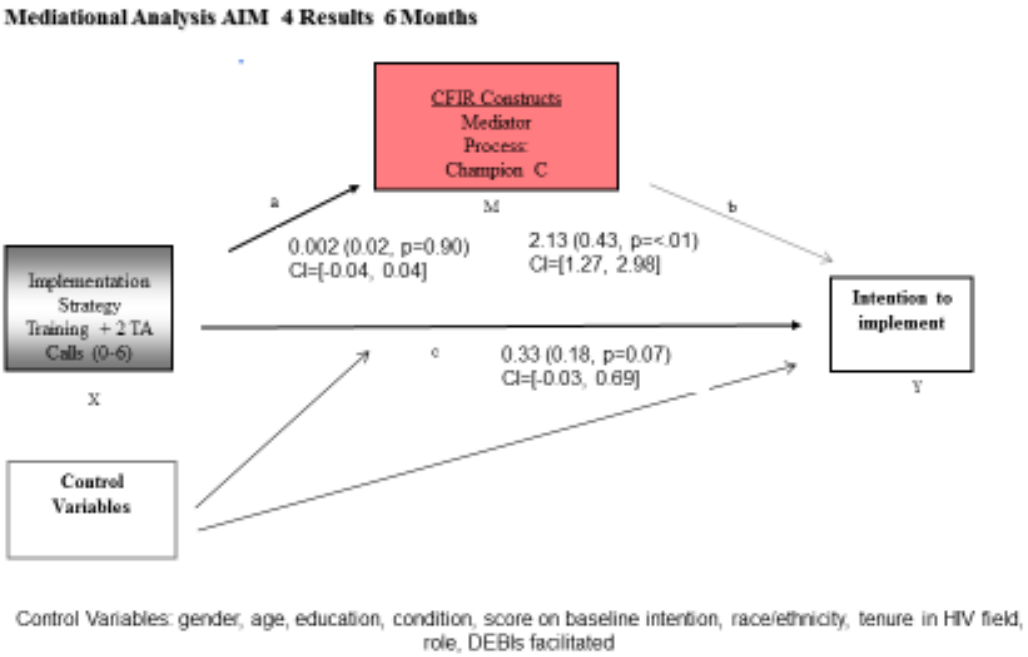
Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment

* p < 0.05

** p < 0.01

*** p < 0.001

Figure 8



For the first step, at 12 months, we did not find a significant effect between the dose of implementation strategy and intent: (β = 0.40, SE = 0.19, df = 120.07, p = 0.03, 95% CI = 0.03 to 0.77). For the second, there was a non-significant relationship between the dose of implementation strategy and the mediator staff perception of an intervention Champion within the organization: β = 0.002, SE = 0.02, df = 1322.1, p = 0.90, 95% CI = -0.04 to 0.04) (See Table 15, Figure 9). For the third step, there was a significant relationship between the mediator and the outcome variable intent: β = 0.14, SE = 0.02, df = 317.51, p < 0.001, 95% CI = 0.09 to 0.19) (See Table 15, Figure 9). For the fourth step, we evaluated when the mediator was added to the model, the relationship between dose of implementation strategy and intent was reduced: β = 0.20, SE = 0.15, df = 586.68, p = 0.18, 95% CI = -0.10 to 0.50) (See Table 15, Figure 9). This is an important finding to note the perception of a Champion was not directly impacted by

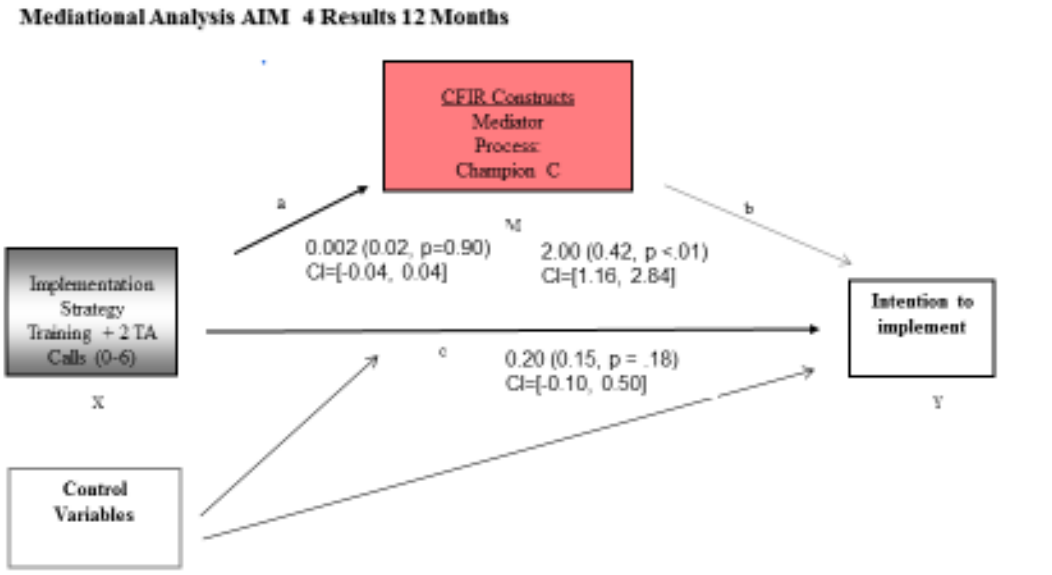
the dose of implementation strategy. However, the b pathway demonstrated a significant relationship between the mediator and the outcome (p=<.0001), Without the statistically significant relationship between the implementation strategy dosage and the outcome intention at 12 month nor in the relationship with the mediator staff perception of an intervention Champion, we do not find a full or a partial mediating effect. (See Table 15, Figure 9). Again as at six months, the association between the mediator and intention is confirmed an important factor to address to enhance implementation.

Table 15 Mediation analysis for Aim 4: Intervention Champion at 12 months

Variable	Model 1			Model 2		
	Parameter estimate	Standard error	95% CI	Parameter estimate	Standard error	95% CI
Intercept	4.18**	1.51	1.22-7.16	4.12**	1.56	1.07-7.17
Training	0.25	0.16	-0.06-0.56	0.20	0.15	-0.10-0.50
Champion				2.00***	0.43	1.16-2.84

Models adjusted for age, sex, race, education, yrs in employed in HIV service, ever facilitated DEBIs, baseline intent to implement Connect, condition assignment
* p < 0.05
** p < 0.01
*** p < 0.001

Figure 9



Control Variables: gender, age, education, condition, score on baseline intention, race/ethnicity, tenure in HIV field, role, DEBIs facilitated

Discussion

The Consolidated Framework of Implementation Research (CFIR), which brings together 19 theories and their domains to guide the examination of determinants of implementation of innovation, was useful in guiding the choice of mediating variables as defined by the inner setting level, the individual implementer, the intervention characteristics and organizational process, and well as to evaluate and interpret the findings and implications for practice and future research. Guided by CFIR, empirical findings of the parent study identifying training and supervision needs as a staff concern for implementation (Witte et al., 2014), consideration of the current literature on implementation strategies and couples-based HIV prevention we suggest this study was a next step in understanding individual level factors that may increase intention to implement a couples-based intervention. While the implementation strategy dosage was found to be associated with intention to implement at 6 months, and the mediators were found to be significantly associated with intention, we need differing measures and design to capture how this implementation strategy of training and TA may be addressing these important mediators. In AIM 1, we found that exposure or dosage to an implementation strategy, which included 4-days of classroom training followed by two technical assistance calls at two and four months, was positively associated with the intention of staff to implement a couples-based HIV/STI prevention intervention in the next 6 months, at 6 months but lost significance at 12 months. Meaning the more days of training and technical assistance attendance and contact the more likely staff were to report intention to implement within the next six months. Intention was considered a proxy for actual implementation for this study given the strong base of evidence demonstrating the relationship between intention and utilization of a new behavior or innovation (Ajzen, 1991; Fishbein & Ajzen, 1977; Gollwitzer & Brandstätter, 1997; Webb & Sheeran, 2008). Statistical significance was lost at the 12 month follow-up. The loss of statistical significance at the 0.05 level at 12 months may indicate the urgency of post-implementation strategy follow-up to support and bolster implementation. Additionally, respondents' baseline intention to implement Connect in the next six months was found to be significantly associated with intention at the

12 month follow-up but not at the 6 month follow-up. This may suggest that changes in intention did occur following the implementation strategy then returned to their initial level in the course of the next six months highlighting the temporal nature of intention as related to this implementation strategy training and two TA calls. Additional calls, booster trainings and/or site visits might be considered as additional components of this implementation strategy. Organizational pre-implementation planning may nurture the intent through immediate action steps post training in addition to the post-training technical assistance contacts included in this strategy. Dosage is an important factor when examining cost efficiency. Given that training costs are often measured in days per training design (DANYA, 2015), and cost efficient strategies can serve public health needs (Eiraldi et al., 2016), web-based training and/or follow-ups may be considered for dose effect comparisons.

For AIM 2, we examined the mediating effect of staff self-efficacy to implement Connect on the implementation strategy dosage and found a-significant relationship between the mediator self-efficacy and the outcome intention to implement Connect in the next 6 months at both 6 and 12 months, even though the implementation strategy dosage was not significantly associated with the staff report of self-efficacy. Social Cognitive theory states that self-efficacy occurs when individuals have an opportunity to learn and practice skills (O'Leary, 2001; Webb & Sheeran, 2008), and that new behaviors are implemented and sustained based on the strength of one's self-efficacy related to the new behavior. Self-efficacy is long understood as a mediator of behavior change (Webb & Sheeran, 2008) and of staff training (Saks, 1995). Findings confirm the importance of staff self-efficacy as it appears to explain and drive intention to implement the couples-based intervention. This study affirms the important construct of individual self-efficacy on the path to adoption of a new method such as couples-based HIV/STI prevention, while highlighting the need to measure differently how the implementation strategy may be impacting this individual implementer characteristic beyond dosage.

Greater examination of implementers' needs and perception of self-efficacy to implement before and during training beyond dosage may increase our understanding of this mediator and impact of training and/or technical assistance. This suggests the need to engage potential implementers in their reasons and commitment to participation as active learners. Finding a significant relationship between previous experience with EBIs, with higher education and greater age and implementation of other EBIs within the organization suggests an opportunity to more closely tailor strategies for those who may or may not have been previously exposed to this EBIs and this dyadic modality. In the staff implementer selection process previous experience should be examined. Pairing those who have had experience with newer staff for peer learning through observation and feedback (Bandura, 1986; Fixsen et al., 2009) could serve efficiency and sustainability within organizations. An implementer assessment in pre-training could directly ask staff their motivations and needs related to self-efficacy.

For AIM 3, while the findings did not capture a mediation effect of favorable perception of the Connect couples-based intervention on the dosage of the implementation strategy and intention to use the program at both 6 and 12 months, it did suggest a significant association between the IC and the outcome intention. This affirms the importance of the CFIR and DOI construct highlighting intervention attributes in the pathway to implementation. Dosage was not associated with the mediator IC, and an alternative measure to capture the effect of the implementation strategy beyond dosage is needed. The use of the favorable perception of intervention characteristics scale combining the five DOI constructs (Dearing, 2009; Rogers, 2003) appeared effective in capturing the perception of the couples-based intervention. A measure of these factors as embedded in the implementation strategy might better help explain if there is a relationship between the implementation strategy and the IC. The implementation strategy may be partially responsible for reducing perceived barriers that enhance positive perception of intervention characteristics through the training and TA content and available implementation resources.

An important next step, not included in this study design, is to better understand the many organizational factors known to predict implementation and may nurture or reject an individual staff members' initiation of discussions in the months following an implementation strategy. For AIM 4, we did not find a statistically significant relationship between the implementation strategy dosage and the mediator perception of the availability of an intervention Champion at the 6 or 12 month follow-up. Of importance, we did confirm the significant association between the mediator and intention to implement as an important factor potentially increasing actual implementation.

Examining how a perception of the availability of an intervention champion might be engaged in an early initiation phase could take advantage of this confirmed factor supporting intention to implementation. We did not measure the type of champion or perceived quality of champion, but rather the first step in identifying the perceived presence of a champion. Leadership and the intervention champion (Aarons & Sommerfeld, 2012) roles for engaging innovation, organizational culture and organizational policies should be considered prior to training and more directly after training during technical assistance. Considering the temporal finding of intention in this study, organizational commitment and leadership are needed to support staff early initiation, intention and excitement for an innovation such as Connect as a couples-based HIV prevention intervention. Enhancing our understanding of the relationships and confirmed importance of individual level factors associated with intention such as the self-efficacy to implement this specific innovation, favorable perception of the intervention while engaging and linking organizational processes through an intervention Champion provides the opportunity to increase the number of adopters for couples-based approaches, using training content and TA tailored to address these implementation factors and related anticipated barriers (Collins et al., 2006; Owczarzak & Dickson-Gomez, 2011).

Chapter V:

SUMMARY, CONCLUSIONS and RECOMMENDATIONS

Summary

Using the Consolidated Framework of Implementation Research (CFIR) which incorporates contribution from Social Cognitive Theory, the Diffusion of Innovation Theory (DOI), and the Theory of Planned Action, this study found that exposure to an implementation strategy, which included 4-days of classroom training followed by two technical assistance calls at two and four months, was significantly associated with the intention of staff to implement a couples-based HIV/STI prevention intervention within the next six months. The CFIR brings together multiple theories and domains to guide the examination of determinants of implementation of innovation. Social Cognitive theory states that self-efficacy occurs when individuals have an opportunity to learn and practice skills, and that new behaviors are implemented and sustained based on the strength of one's self-efficacy related to the new behavior. Studies have identified the strong association between an innovation's characteristics defined by DOI theory as perceived by potential adopters and the likelihood of utilization of that innovation (G. A. Aarons, 2005; Smith & Manfredo, 2011). DOI posits that one predictor of adoption is the individual level users' endorsement of five attributes of the innovation: relative advantage, compatibility, complexity, trialability and observability (E. M. Rogers et al., 2005). Using this five variable scale we were not able capture a significant association between the dosage effect of the implementation strategy on this mediator positive perception of the intervention but did, however, identify a significant relationship between this mediator and the outcome intention to implement at 6 month follow-up. This important and significant association was confirmed between the mediator and the outcome intention. This was also true for the organizational process construct perceived intervention Champion in the organization and for individual staff perception of their self-efficacy to implement the couples-based intervention. Further examination beyond dosage is needed to understand how the training and TA may have impacted the

individual staff member's assessment of their self-efficacy to implement, their positive perception of the intervention and their perception of the availability of an intervention champion.

It is important to note that the implementation strategy combined four core components of implementation in the training and TA design and content known to promote learning and skills needed to implement (Fixsen et al., 2005; Joyce, 2002). These included knowledge, theory or rationale for the new skills, strategy or intervention in the training, incorporating facilitator modeling of skills and the opportunity to practice the skills and content of the intervention. Finally, peer coaching, the fourth component, is the collaborative work of implementers in planning to implement the training content effectively. Additionally, quality assurance/quality improvement (QA/QI) training content was incorporated to reinforce the proper use of the tools, training, and accessing TA for quality performance (Bandura, 1986; Joyce, 2002). Greater examination of how the planned strategy's activities and content impact the three mediators beyond dosage is needed while recognizing exposure is associated with intention to implement.

Conclusion

Study Limitations

Findings should be understood taking into account several limitations. The majority of implementation outcomes are underdeveloped, yielding few instruments or those without evidence of psychometric strength. Without high quality instruments, it can be difficult to determine predictors, moderators, and mediators of implementation with exacting rigor. There is a need for additional standardized instruments to better capture the multi-levels of implementation constructs (Lewis et al., 2015). Operationalizing variables such as intention or intervention champion with only one item is not ideal but is commonly utilized due to the afore mentioned measurement limitations (Damschroder, Banaszak-Holl, et al., 2009; Fishbein & Ajzen, 2010; Gollwitzer & Brandstätter, 1997; Guttmacher, 2010). A scale with high reliability was utilized for the mediator Favorable Perception of Intervention

Characteristics scale to combine multiple constructs into one measure. Additional questions regarding the participant's current capacity to work with couples beyond a single item of self-efficacy can inform changes in self-efficacy over time based on certain core couples-based skills.

Data was based on a non-random, New York regional population sample and is self-report, which can be affected by poor recall. New studies that include more complicated statistical models including multiple independent variables, multiple mediators, and multiple outcomes simultaneously could be considered to further inform the most effective bundling of implementation strategies and for targeted subgroups. More comparisons of mediated effects and multilevel models may be especially informative as progressive statistical methods not as reliant on p-values make analysis possible (MacKinnon, 2011; MacKinnon, Fairchild, & Fritz, 2007; Raudenbush & Sampson, 1999).

Study Innovation

To our knowledge, the parent study was the first study to examine utilization of a multi-session, couples-based, behavioral approach to HIV/STI prevention comparing two implementation methods. This study builds on this work to look closer for the first time at inner domain constructs impacting the intent of individual staff members to utilize a couples-based approach to HIV/STI prevention. Given the low adoption of couples-based approaches to HIV/STI prevention, only 3 CDC-funded agencies for Connect in the US, this study advances the field's knowledge of factors that may be highlighted in the support of this dyadic approach to HIV/STI prevention through the design of training and technical assistance activities. This is the first study examining training dosage and mediators associated with intention to implement couples-based methods in HIV/STI prevention. By supporting administrators and front-line staff together in a training plus technical assistance approach, frontline staff with strong self-efficacy and a favorable perception of the intervention may advocate for agency implementation through a champion or by becoming a champion themselves. By understanding the need to better assess the implementation strategy's effect beyond dosage of this classroom training and two TA call approach, decisions regarding

bundling of implementation strategies to enhance efficiency and effectiveness are more informed. Intention to change or implement a new behavior has been commonly integrated into most behavior change theories (Ajzen, 1991; Fishbein, 1975; Gollwitzer & Brandstätter, 1997), and is strongly associated with self-efficacy or control over a new behavior. There are no studies at present that examine the intention or self-efficacy to implement a couples-based HIV/STI prevention intervention.

Using quantitative methods we captured a significant relationship between staff exposure to training and utilization of technical assistance and intention to implement. Longitudinal data at 2 time points allowed for modeling which provided insight into the strength of initial intention at six months post strategy to implement a new innovation and the eventual waning at 12 months. Specific exploration of mediators linking inner setting factors at the individual and organizational level and the relationship to dosage and intention provided confirmation of the importance of these mediators on intention to implement while pointing to the need for further measurement of the implementation strategies training and technical assistance beyond dosage to target these domains to enhance adoption of innovations. Using data derived from the parent study sampling approach served to access AIDS services organizations across New York State resulting in a broad continuum of organizational capacity, providing generalizability of study results to a diverse population of HIV prevention service providers. Furthermore, the inclusion of both community-based and hospital-based programs gives evidence of the implementation strategy dosage effect with staff from diverse settings without being tailored to an organizational context. The study uses statistical methods to comprehensively explore the role of inner setting constructs and perception of intervention characteristics. This study provides insight into methods and implementation strategies often bundled to promote adoption and implementation of couples-based HIV/STI prevention approaches which have been, thus far, slow to actualize in the U.S.

Recommendations

Implications for Practice

The findings of this research directly informed the design and implementation of HIV prevention efforts to disseminate couples-based behavioral interventions in the U.S. In 2016, the Social Intervention Group with the CDC launched a national diffusion plan to enhance the uptake of an adapted version of the Connect intervention called, Connect ^{HIP}: A Couples-level, High Impact Prevention Intervention for MSM, Transgender and Heterosexual couples living with or at-risk for HIV/STIs. Findings from the parent study along with this inquiry informed technical assistance and the 3-day training design I authored and is cleared by the CDC for dissemination to be utilized in this intervention package. External change agents, such as national capacity building trainers assigned to Connect ^{HIP}, along with their implementation partners, may consider efforts to address these mediating factors knowing their relationship to intention to implement. Attention to contacts during pre-planning and training to address these mediators may serve to enhance the likelihood of successful adoption. Attention to the availability of direct contact and engagement of implementers in training and technical assistance which are tailored to the needs of the trainees may increase intention to implement, but additional strategies are needed to fully shepherd programs toward actual implementation. Strategies should include pre-training consultation on organizations readiness, consideration of an intervention champion, as well as, decisions about staff selection and their evaluation of current self-efficacy to implement with couples (Fixsen et al., 2009). Staff perception of the intervention pre- and post-training and their sense of control over decisions about implementation should be attended to throughout the implementation strategy activities. Since intention associated with the implementation strategy dosage decreased at 6 months, additional activities could be designed post-training to engage decision makers and trained staff in moving implementation forward. Some researchers have identified the effectiveness of implementation teams (Fixsen et al., 2005) charged with the responsibility of shepherding the innovation toward adoption.

Implications for Policy

The CDC has demonstrated their support for couples-based HIV prevention having kept it on the compendium of best-evidenced interventions supported through capacity building and funded the replication of Connect and adaptation of Connect^{HIP}. Capacity building strategies and plans informed by the relationship between exposure and greater intention to implement should allow for resources to make contact available with potential implementers, and to consider how the mediators related to intention are to be addressed, either in-class or web-or phone-based. Booster training, when funded, giving attention to mediating factors highlighted in this study could increase implementation outcomes for couples-based approaches to HIV prevention and care.

Implications for Research

As noted, there is a growing interest in using progressive statistical methods to examine the "how" an intervention or implementation strategy works. Mediation analysis findings may identify certain intervention or implementation strategy components that need to be abandoned or strengthened, as failures to significantly alter mediating variables occur either because the strategy was ineffective or the measurements inadequate. In this case, the mediators were not significantly impacted by the dosage of the strategy, or potentially we were not powered to capture this relationship adequately. Additional comparative analysis may be considered for future study using an alternative analytic approach and interpretation not as reliant on p-values informed by Mackinnon and Shrout (MacKinnon, 2011; Shrout, Shrout, & Bolger, 2002). The American Statistician's Association has challenged the field to look beyond the p-value at 0.05 to interpret the size of effects (Wasserstein & Lazar, 2016) by taking into account confidence intervals, understanding the phenomenon under examination and to interpret results within the context. Additional measures of intention that capture subjective norms and attitudes including the perception of the individual staff member's control over implementation are needed to understand implementation strategies post-training that take into account organizational resources like supervisors to

increase staff self-efficacy, fidelity and sustainability of an interventions implementation (Eiraldi, 2014). Further examination of the role and effectiveness of the intervention champion, beyond solely the presence or absence of, would further inform activities to identify and mentor the champion, and to design bundled strategies with training and technical assistance to include components that directly engage the organizational context pre- and post-training and technical assistance. Finally, the decrease in HIV prevention funding has broadened an interest in distance learning for efficiency. Greater understanding of the effectiveness of couples-based prevention online training as compared to classroom and technical assistance would be informative for future capacity building designs that maintain dosage while reducing in-class training and travel associated. Comparative effectiveness and adaptive study designs could examine the effect of in-class versus online activities pre- and post-training on these mediators and outcome of actual or intention to implement. Examining how some implementers may significantly benefit from quality skill-based training and require less frequent technical assistance or coaching while another implementer may leave the pre-implementation training a little confused and require significant on-the-job coaching from their immediate supervisor rather than technical assistance from external agents.

This research contributes to our understanding of implementation strategies utilized to support utilization of evidence-based interventions for HIV prevention with couples. While couples-based HIV prevention and treatment adherence interventions have shown effectiveness, the utilization of this dyadic method has lagged behind. Having demonstrated that dosage of this combination training and technical assistance implementation strategy was significantly associated with intention to implement, further research is needed to examine the relationship of intention and actual implementation. Since we observed that staff perception of their self-efficacy, positive perception of the intervention and availability of an intervention champion was significantly associated with intention further understanding is needed to inform the effect of training and technical assistance on these factors in the causal pathway beyond the dosage effect. A training and TA scale could be developed informed by the mediator constructs to

examine the strategies effect on the mediators. Additionally, research examining individual differences associated with self-efficacy and post-implementation strategy variables within the implementing context may provide opportunity for strategies to be adaptive to the intensity, nature and duration of a strategies components.

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Appendix A

Analysis of Variance Inflation for Control Variables

Appendix B

Pearson Correlation Coefficients

Appendix C

Perception of Cost and positive perception of the intervention

Appendix D

Correlation Analysis of Independent Variables