






# Leveraging Randomized Controlled Trial Design: HIV and Wellness Interventions with Marginalized Populations

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## Abstract

Treatment as usual has historically been used as control arms for randomized controlled trials (RCTs), but utilizing wellness interventions as active comparison conditions can advance the evidence base of such interventions while increasing access to health promotion content. We use the results from the CONNECT 2 RCT's wellness intervention control arm as a case example of active comparison conditions that can control for dosage or attentional effects in future research. We summarized existing studies on wellness control HIV RCT interventions, introduced CONNECT 2, and discussed recruitment, randomization, and the intervention. Overall, Wellness Promotion participants were more likely to engage in physical activity, eat healthier, and do more vigorous exercise when compared with HIV Risk Reduction. CONNECT 2 Wellness intervention results solidify why wellness interventions can play an important role in treatment guidelines. Developing and implementing this model can be a more ethical, equitable, and holistic approach among underserved communities.

## Keywords

equipoise, research ethics, health equity, health promotion, control arm, randomized control trial, wellness interventions

The gold standard for evaluating intervention effectiveness is randomized controlled trials (RCTs) (Hariton & Locascio, 2018), but RCTs that include wellness or health-promotion behavioral interventions as control conditions and whose emphasis and core components or outcomes are neither specific to mental health nor conducted in education or work settings are limited and rare, especially in interventions developed by social workers. Researchers have moved away from using “placebo” as a control in which the participant received no intervention and have instead evolved to providing Treatment as Usual (TAU) (Oberjé et al., 2015). TAU is now widely used as a control arm for many RCTs, especially HIV/AIDS or substance misuse prevention interventions. Although there has been some shift to using TAU as a control condition in recent years (Freedland et al., 2011), not much attention has been paid to improving control conditions (Burns, 2009; de Bruin et al., 2009; Freedland et al., 2011). Few researchers have developed alternatives to TAU, and of those who have, there have been even fewer published outcomes and lessons learned from their interventions (Oberjé et al., 2015). With the increase in emphasis on mental and physical health, there is an urgent need to address physical/mental health in the control condition, especially

among marginalized communities (Pratt, 2019), but little is known about how wellness interventions can improve study participants' physical and mental health, especially those most at risk for chronic disease.

Wellness is defined as “the quality or state of being in good health, especially as an actively sought goal,” and wellness is considered achieved “when someone strives for balance in their life by constantly making choices to further their health and fulfillment” and has proven to have a “direct influence

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on overall health” (Evans, 2014; Merriam-Webster, 2019). Thus, wellness promotion can be defined as “the enhancement of physical, mental, and social well-being and the prevention of disease and disability” (Nader, 1992, p. 485). In contrast, health promotion is defined as “a behavioral, social science that draws from the biological, environmental, psychological, physical and medical sciences to promote health and prevent disease, disability, and premature death through education-driven voluntary behavior change activities that are strategies to improve health knowledge, attitudes, skills and behavior” (Khudair, 2018, p. 1677). Studies on this topic have sometimes used either health promotion or wellness interchangeably, but we recommend consistent use of terms in future research. Throughout this paper, we will use the term wellness for clarity and consistency.

### *Substance Use, Chronic Disease Co-Occurrence Among Low-Income Communities in the United States*

Drug use and a lack of access to care for chronic diseases are two leading causes of poor health outcomes among low-income minority individuals (Hibbard & Greene, 2013). The relationship between illicit drug use and a broad spectrum of chronic diseases is complex and multifaceted. Growing evidence suggests that substance use also impairs judgment and negotiation skills, resulting in an increased risk of engagement in poor health behaviors (Freudenberg & Heller, 2016). Excessive alcohol consumption is directly related to chronic diseases, including diabetes, cancer, digestive problems, heart disease, and many other medical ailments (2013). Additionally, drug-involved populations often suffer poor health outcomes, such as the increased risk of obesity, heart attack, diabetes, HIV infection, intimate partner violence, alcohol abuse, hypertension, and even death (Whiteford et al., 2013).

Substance use and chronic disease are co-occurring public health threats that disproportionately affect low-income urban populations living in the United States (Dumont et al., 2012; King et al., 2018; Webb Hooper et al., 2020). Most research among people who use drugs has focused on reducing the risks for HIV and sexually transmitted infections (STIs) and substance use (Leigh & Stall, 1993; Turan et al., 2019). However, many drug-involved individuals report poor nutrition and physical fitness, and few meet basic wellness promotion guidelines as defined by the Centers for Disease Control (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2013). Regardless, few intervention researchers have focused on general wellness and other health outcomes for drug-involved populations despite their high risk for heart disease, diabetes, and other significant chronic diseases related to stress, diet, and lack of exercise—and, more recently, COVID-19 (Cunningham et al., 2017; Killerby et al., 2020; Kim & Bostwick, 2020; MacDonald, 2012; Noonan et al., 2016; Stokes et al., 2020; Wadhwa et al., 2020; Yancy, 2020).

The dilemma of the underrepresentation of minorities in clinical research is an ethical strategy to reach and engage more diverse populations in HIV research and other clinical and translation research (Luchenski et al., 2018; Pratt, 2019; Yu et al., 2021).

### *Applying a Wellness Intervention as a Strategy to Address Co-occurring Substance Use and Chronic Disease Burdens Among Marginalized Groups*

We present a methods paper that supports the principle of equipoise in clinical research, with a lens on integrating wellness interventions into an experimental “control” condition and as a scientific strategy to help address social determinants of health among marginalized groups, including people who use drugs, individuals involved in the criminal legal system, and those at risk for HIV (Jackson et al., 2016). Marginalized groups have been historically difficult to recruit and retain in clinical trials due to their transient nature, heavy supervision requirements, and facilitator training required (Martinez et al., 2014; Witte et al., 2004; Wu et al., 2005). The current study adds to this limited literature by presenting the intervention and results from an RCT and successful strategies and recommendations for designing and implementing wellness-focused RCTs as control arms. We use the wellness intervention control arm for CONNECT 2, an RCT focused on HIV/STI risk reduction for low-income, drug-involved couples, as a case example to guide this proposed strategy for future interventions. Intervention design and future recommendations presented here may help guide other interventionists to implement RCTs with wellness control arms in low-income minority communities.

### *Implications of Wellness Interventions in Response to Social Determinants of Health*

Social determinants, such as high-crime residential neighborhoods, lack of employment and low-wage employment, lack of doctors in low-income minority neighborhoods with affordable care options, lack of health insurance, and lack of affordable housing also predispose low-income urban minorities to poor health and chronic diseases (Geronimus, 2000; Rashid et al., 2009). It is well documented that these adverse social determinants can lead to lower life expectancy and that inequities in health outcomes worsened disproportionately among underserved populations due to the COVID-19 pandemic (Anderson, 2012). In addition, structural racism, including racialized drug laws, has further increased the relative risk of Blacks and Latinx Americans being arrested, convicted, and incarcerated for the same drug-related crimes as whites (Beckett et al., 2005; Kerr & Jackson, 2016). Incarceration further contributes to poor health due to lack of exercise, an unhealthy diet, and interrupted access to regular healthcare services (Zenk et al., 2011).

Two longitudinal observational studies examining county- and census-tract-level associations between social determinants and HIV diagnosis among African-Americans have identified potential moderators of HIV/STI incidents (Gant et al., 2012, 2014). Researchers found that among heterosexual African-American men, rates of HIV varied with increases in housing vacancy, lower educational attainment, and a higher number of non-married individuals in their census tract over a four-year period (Gant et al., 2014). An opposite trend in HIV rates among these men was observed in areas with a greater number of unemployed and married individuals. For African-American women, an increase in incidents of HIV was observed at the county level over two years in areas with greater income inequality and a higher number of unmarried individuals (Gant et al., 2012, 2014). A reverse in the trend was observed for those women residing in counties with a greater proportion of white individuals.

These adverse conditions also have implications for negative outcomes associated with substance use and HIV. For instance, unemployment, housing insecurity, and residing in high-crime areas can place individuals with histories of substance use at risk of relapse (Goldman-Hasbun et al., 2019). In addition, the stress and coping demands of challenging social conditions can be a risk factor for substance use and alcoholism, both of which may reduce inhibitions associated with sexual risk and HIV prevention behaviors (Pence et al., 2008). In addition, substance use has been associated with low adherence to HIV medication (Gonzalez et al., 2013).

### *Correlations Between Substance Use and Chronic Health Implications*

Steady increases in the prevalence rates of opioid and methamphetamine use over the past five years have worsened since the COVID-19 pandemic, and emerging data suggest that Black individuals have been disproportionately represented in overdose deaths (Alexander et al., 2020; Becker & Fiellin, 2020; DiGennaro et al., 2021; Khatri et al., 2021; Larochelle et al., 2021). Therefore, for minority populations overrepresented in COVID-19 infection rates—including Black populations (Webb Hooper et al., 2020)—there is a critical need to not only reduce the risk of substance use (McKnight-Eily et al., 2021) and HIV/STIs but also to address the co-occurring risks of chronic disease, including poor eating habits, which compound health consequences, are a leading contributor to premature death in this population, (Centers for Disease Control and Prevention, 2001; Tai et al., 2021; Webb Hooper et al., 2020) and increase the risk for poor COVID-19 outcomes (Killerby et al., 2020; Nanda et al., 2021; Stokes et al., 2020; Yancy, 2020). Lastly, the COVID-19 pandemic and its associated restrictions have increased the disparity of health outcomes and exacerbated many social determinants of health. For example, some healthcare services for non-COVID-19-related conditions were unavailable, restricted, or disrupted for

periods of time (Bojdani et al., 2020; Ferreira-Filho et al., 2020).

In Table 1, we present data on all SIG Wellness interventions as control conditions for RCTs. Information is provided on Wellness Components, theory, sample and settings, study and intervention design, and details on the follow-up period and retention rate for each study.

## **Literature Review**

### *HIV Treatment RCTs with Wellness Intervention Including Couples-Based Wellness Interventions*

We identified very few HIV/STI risk reduction RCTs that utilized wellness or health promotion interventions as control conditions (Abe & Abe, 2019; Harawa et al., 2020; Heeren et al., 2018; Oliveira et al., 2020). Despite their clear promise to promote health and prevent or improve HIV outcomes, there is a lack of consensus on how wellness is defined across the few articles written to date. Definitions range from increased service accessibility (Harawa et al., 2020) to healthier lifestyles (e.g., healthy eating and increased exercise) and risk mitigation (e.g., decreased alcohol consumption) (Heeren et al., 2018; Oliveira et al., 2020). Target populations also differ from those at risk for HIV and other STIs (Harawa et al., 2020) to those living with HIV (Oliveira et al., 2020). In the African-American couples study, Eban both arms—HIV/STI risk reduction (intervention) and wellness/health promotion (control)—used a similar structure, which focused on increasing healthful behaviors, including physical activity, healthy eating, early detection and screening, improving medication adherence, and reducing alcohol and cigarette use (El-Bassel, Jemmott, et al., 2011; EBAN NIMH Multisite HIV/STD Prevention Trial for African American Couples Group, 2008a, 2008b, 2008c, 2008d). EBAN was developed using social cognitive theory and had an emphasis on a relationship-oriented ecological framework and Afrocentric paradigms, with an emphasis on improving behavioral intention, self-efficacy, and effective communication and problem-solving skills, which are key to mitigating chronic health conditions (El-Bassel et al., 2016; El-Bassel, Jemmott, et al., 2010). To ensure appropriateness for the target population of African-Americans with HIV or a partner living with HIV, the study tested both the efficacy of an HIV/STI intervention aimed at reducing risk among serodiscordant African-American couples and the efficacy of a health promotion intervention in addressing targeted knowledge regarding heart disease, hypertension, stroke, and certain cancers, and behavioral skills to address wellness outcomes to the population, and specifically included chronic health concerns, equity, and access issues (El-Bassel, Gilbert, et al., 2010).

A growing body of research indicates the potential effectiveness of couples-based interventions for improving health outcomes (El-Bassel et al., 2019; El-Bassel, Gilbert, et al., 2010,

**Table 1.** Social Intervention Group (SIG) Wellness Studies Comparison.

Intervention	Wellness Components	Theory	Sample and Setting	Design	Follow-up Period and Retention Rate	Findings
EBAN (El-Bassel, Gilbert, et al., 2010; El-Bassel, Jemmott, et al., 2010)	Addressing wellness specific to the population. The wellness intervention specifically included chronic health concerns and equity and access issues. Focused on behaviors of individuals, not couples—risk of heart disease, hypertension, stroke, and certain cancers. It was designed to increase fruit and vegetable consumption, physical activity, and medication adherence, including HIV medication adherence.	Social cognitive theory	535 randomized couples African-American HIV serodiscordant heterosexual couples in Atlanta, Georgia; Los Angeles, California; New York; and Philadelphia, Pennsylvania.	EBAN tested both the efficacy of an HIV/STD intervention aimed at reducing risk among serodiscordant African-American couples and the efficacy of a health promotion intervention. 8 weekly 2-h session	- 91.4% of Couples in HIV/STD couple arms attended all sessions. - 84.1% of those in the wellness arm attended all sessions. - 87.3% completed Immediate postintervention. - 80.9% 6-month follow-up retention rate. - 81.9% were retained at the 12-month follow-up.	Proportion of condom-protected intercourse acts was larger among couples in the intervention group than in the comparison group. The adjusted percentage of couples using condoms consistently was higher in the intervention group (63%) than in the comparison group (48%). The adjusted mean number of unprotected intercourse acts was lower in the intervention group than in the comparison group. The cumulative STI incidence over the 12-month follow-up did not differ between couples in the intervention and comparison groups. The overall HIV seroconversion at the 12-month follow-up was 5 (2 in the intervention group, 3 in the comparison group) of 535 individuals, which translates to 935 per 100,000 population.
CONNECT 2 (El-Bassel, Gilbert, et al., 2011; El-Bassel, Jemmott, et al., 2011)	Recognizing and developing the self-efficacy needed to increase healthy behaviors, including physical activity, healthy eating, early detection and screening, improved medication adherence, reduced alcohol and cigarette use, and improved communication with primary physicians. - identify and address the circular relationship	Social cognitive theory	489 individuals aged 18–40 who were drug-involved [heterosexual] couples in New York City; conducted between November 2005 and September 2010. Participants were recruited through needle/syringe programs, homeless shelters, street outreach, food pantry/	The intervention sessions were divided into three arms: (1) couple-focused wellness promotion, (2) couple-focused HIV/STD risk reduction, and (3) individual risk reduction. The CONNECT 2 intervention compared a 7-session wellness promotion intervention to a 7-session couple-based	- 489 participants completed the intervention (87% retention rate) - 421 participants completed the 6-month follow-up (75% retention rate) - 428 participants completed the 12-month follow-up	Participants in the Couple Wellness Promotion (WP) arm were more likely than those in the Individual Risk Reduction arm to report improvements in eating habits (35.3 and 31.4, respectively), including eating foods that were steamed or broiled. Couple WP participants were more likely to engage in increased

*(continued)*

Table 1. (continued)

Intervention	Wellness Components	Theory	Sample and Setting	Design	Follow-up Period and Retention Rate	Findings
	<ul style="list-style-type: none"> <li>- between substance use and poor health behaviors.</li> <li>- rest and relaxation</li> <li>- the importance of personal fitness, strength-building, and aerobic exercise, how to check their pulse, how to use a pedometer</li> <li>- assessed and evaluated their current health risks</li> <li>- measured their BMI</li> <li>- taught about nutrition and meal planning, including identifying healthy and unhealthy food options</li> <li>- learned about prevention strategies for common health concerns</li> <li>- how to identify emergency vs. nonemergency medical concerns</li> <li>- how to navigate the healthcare system when looking for a doctor and medical insurance</li> <li>- how to prepare to see a doctor</li> <li>- what they should expect from a doctor</li> <li>- identified any stigmas associated with being a current or recovering drug user; mapped strategies for overcoming the stigma</li> <li>- identified their healthcare needs, barriers, and solutions</li> <li>- learned about the effects of rest and relaxation on health, including the importance of sleep and relaxation on health and well-being</li> <li>- wrote letters to themselves to remind</li> </ul>		<p>bank, and word-of-mouth.</p>	<p>intervention to reduce sexually transmitted infectious diseases and HIV.</p>	<p>- (76% retention rate)</p>	<p>physical exercise during the past 90 days (19.0 and 16.9, respectively), compared to Individual Risk Reduction participants.</p> <p>Wellness promotion participants were 41% more likely to do rigorous exercise at 6-month compared to Risk Reduction participants.</p> <p>The subgroup analysis also found that Couple Wellness promotion participants were 82% more likely than Couple Risk Reduction participants to engage in vigorous activity and were more than twice as likely to engage in light physical activity throughout the study period, when compared to Couple Risk Reduction participants.</p> <p>The full sample of wellness participants was 21% more likely than risk reduction participants to engage in light physical activity. Participants assigned to the Wellness promotion arm were twice as likely to increase vigorous physical activity in the past 90 days from baseline to immediate post-intervention test, and were also more likely to report sustaining an increase at 12-month follow-up compared to the Risk Reduction arm. Wellness participants were also more likely to have eaten healthier food (steamed, boiled) in the</p>

(continued)

Table 1. (continued)

Intervention	Wellness Components	Theory	Sample and Setting	Design	Follow-up Period and Retention Rate	Findings
Connect and Unite (CNU) (Wu et al., 2011)	them of future goals and progress throughout the intervention Behavioral: WP Intervention Attention control condition - WP focuses on nutrition, fitness, healthcare, and stress management. Given the prevalence of health problems among the target population, WP emphasizes adherence to medical guidance and medication regimens.	Social cognitive theory	African-American/Black men who have sex with men (MSM) in same-sex intimate relationships in which at least one partner is illicitly using psychoactive substances in NYC	4 sessions of CNU intervention—90 min each delivered by a facilitator to a single couple.	424 participants randomized to Risk Reduction HIV vs. WP	past 90 days at IPT follow-up, but the increase was not sustained over time.
Computer Women on the Road to Health (WORTH) (El-Bassel, Gilbert, Goddard-Eckrich, et al., 2014; El-Bassel, Gilbert, Terlikbayeva, et al., 2014; Gilbert et al., 2016)	Raising awareness of how interpersonal violence (IPV), substance misuse, and HIV are related; identifying and addressing personal triggers for unsafe sex and drug use; HIV risk reduction problem-solving and negotiation skills; technical condom use skills; IPV screening and feedback; safety planning, social support, identification of service needs and linkage to services, and goal setting for HIV risk reduction and IPV prevention	Social cognitive theory & Empowerment theory	306 women who use drugs and were involved in community corrections in NYC	3-arm RCT including Computerized WORTH, Traditional WORTH, and WP (attention control) delivered through 2-hour weekly sessions over 4 weeks	- 267 participants completed the 3-month follow-up (87% retention rate) - 277 completed the 6-month follow-up (91% retention rate) - 278 completed the 12-month follow-up (91% retention rate) - Retention rates of 87% or higher at all three follow-up assessments did not significantly differ by condition	Among women in Computerized WORTH, rates of all types of IPV and severe IPV victimization in the past 6 months decreased from baseline to the 12-month follow-up. These results were not seen in Traditional WORTH or the WP arm. Compared with WP participants, Computerized WORTH participants were less likely to experience physical IPV, severe injurious IPV, and severe sexual IPV in the 12 months prior. Women assigned to either intervention arm were significantly more likely than women assigned to WP to report an increase in the proportion of protected sex acts with primary, and all partners; odds of consistent

(continued)

**Table 1.** (continued)

Intervention	Wellness Components	Theory	Sample and Setting	Design	Follow-up Period and Retention Rate	Findings
Renaissance (El-Bassel, Gilbert, et al., 2011; El-Bassel, Jemmott, et al., 2011)	The couple-based WP comparison intervention was designed to control for non-specific effects (e.g., modality and dosage). Core components of this psycho-educational intervention focused on maintaining a healthy diet, promoting physical fitness in daily routines, improving access to health care services and drug treatment by identifying and addressing service barriers, learning stress-reduction exercises, and setting and following up on personal health goals. For ethical reasons, this intervention also included the same naloxone-based overdose prevention activity described above.	The couple-based Risk Reduction intervention was guided by social cognitive theory and a relationship-oriented ecological framework.	A total of 300 couples (600 participants) in Kazakhstan where one or both partners reported injection drug use in the past 90 days	Participants were randomized to 1 of 2 arms: (1) a 5-session HIV/HCV/STI prevention intervention (risk reduction: RR) or (2) a 5-session Wellness Promotion intervention (WP)	<ul style="list-style-type: none"> <li>- Couple Risk Reduction</li> <li>- 82.5% completed all 5 sessions</li> <li>- 224 completed 3-month follow-up (76.4% retention rate)</li> <li>- 238 completed 6-month follow-up (82.4% retention rate)</li> <li>- 229 completed 12-month follow-up (81.2% retention rate)</li> <li>- 20 participant deaths</li> <li>- vs. WP</li> <li>- 89.9% completed all 5 sessions</li> <li>- 245 completed 3-month follow-up (85.1% retention rate)</li> <li>- 230 completed 6-month follow-up (81.0% retention rate)</li> <li>- 229 completed 12-month follow-up (84.2% retention rate)</li> <li>- 26 participant deaths</li> </ul>	<p>condom use; and a decrease in the number of unprotected sex acts with primary, and all partners.</p> <p>Over the 12-month follow-up period, assignment to RR compared with WP significantly lowered the incidence of HCV infection by 69%. Although differences were not statistically significant, RR participants had a lower incidence of HIV infection by 51% and STI by 37% than WP participants. RR participants reported significantly fewer numbers of unprotected vaginal sex acts with their study partners and more consistent condom use over the entire follow-up period compared with WP participants.</p>

Note. Findings for Connect and Unite (CNU) were not published.

2011; Gilbert et al., 2018; Jiwatram-Negron & El-Bassel, 2014; NIMH, 2010). However, while couples-based wellness behavioral interventions have shown great promise, their representation among RCTs is minimal (El-Bassel, Gilbert, et al., 2011). One study indicated the effectiveness of couples-based wellness, mental health, and psychological well-being interventions for older couples (Carmack et al., 2021). Findings suggest that interventions addressing depressive symptoms and adherence to HIV medication protocols are more effective with couples than if they were administered to individuals (Shtompel et al., 2020; Tuthill et al., 2019). It is important to note that while, at this time, there is naturally limited literature on how COVID-19 might affect couples-oriented substance use interventions, several studies suggest that the necessary isolation during the pandemic worsened mental health conditions, particularly among people in difficult living and working conditions, as well as those under financial stress (Avena et al., 2021).

### *Utilization of Wellness Interventions as Control Arms*

The Social Intervention Group (SIG) has a long history of using wellness interventions as control conditions for HIV/STI behavioral health RCT interventions and culturally tailoring these interventions. Project EBAN included significant Community Advisory Board (CAB) involvement from study design through implementation and interpretation of results, and the intervention staff was reflective of the participants (Mott & Crawford, 2008). EBAN laid the groundwork for additional SIG wellness control interventions, notably CONNECT 2 (described here) in this paper, Connect “N” Unite (Wu et al., 2011), WORTH (El-Bassel, Gilbert, Goddard-Eckrich, et al., 2014), Project Renaissance (El-Bassel, Gilbert, Terlikbayeva, et al., 2014) and, more recently, a peer-based HIV self-testing study among HIV-uninfected female sex workers who inject drugs in Kazakhstan (National Institutes of Health, 2022). While we will not be discussing all of these interventions in this paper, it is worth noting that modifications were made to adapt each wellness intervention for demographic/population differences. Table 1 compares these interventions, the wellness components employed, and other key study details.

In response to the urgent need to deploy proven chronic disease prevention efforts among low-income men and women who use drugs, this paper reports on outcomes from a wellness intervention that served as one of the comparison conditions in Project CONNECT 2, a NIDA-funded HIV/STI Prevention Trial that tested the efficacy of an HIV/STI risk reduction intervention for drug-involved couples in New York City and was previously published (El-Bassel, Gilbert, et al., 2011). The Wellness arm of the CONNECT 2 RCT was designed to increase healthy behaviors, including increasing physical activity and healthy dietary practices, reducing and ceasing alcohol use, practicing early detection, reducing stress, improving medication adherence for hypertension, and improving communication with primary

physicians (El-Bassel, Gilbert, et al., 2011). Table 2 outlines the Wellness Intervention components. We hypothesized that couples assigned to the seven-session wellness promotion intervention that served as an intentional comparison condition would have better nutrition and more physical activity than couples assigned to the seven-session couple-based intervention to reduce STIs and HIV (El-Bassel, Gilbert, et al., 2011).

### **Method**

This paper presents an analysis of the effectiveness of a wellness intervention used as an RCT control arm in a population of heterosexual adults in New York City in an intimate relationship in which at least one person had recent HIV and substance use risk factors. An evaluation of the intervention effect on outcomes among the three RCT arms of CONNECT 2 has been reported elsewhere (El-Bassel, Gilbert, et al., 2011). In this paper, we present measurements and study designs used to analyze the efficacy of wellness interventions as control arms when compared to other intervention arms in RCTs.

### *Design*

We conducted the CONNECT 2 RCT between November 2005 and September 2010 in New York City. The Institutional Review Board of Columbia University approved the study. Research assistants recruited participants through needle/syringe programs, homeless shelters, street outreach, food pantry/ food bank, and word-of-mouth (El-Bassel, Gilbert, et al., 2011). We screened 1,116 individuals, and 282 heterosexual couples were randomized. Eligibility criteria for couples included: (1) both were 18 years of age or older, and at least one partner was between the ages of 18–40; (2) both tested HIV-negative using OraQuick and OraSure assays; (3) both identified each other as their main sexual partner; (4) both reported being together for at least six months; (5) both reported that they intended to remain in a relationship for at least one year; (6) at least one partner reported using illicit drugs in the prior 90 days and was seeking or currently in drug treatment; (7) at least one partner reported having had unprotected intercourse with the other in the prior 90 days; (8) at least one partner had one or more HIV risk criteria. More details on HIV risk criteria are described in a previous publication (El-Bassel, Gilbert, et al., 2011).

We randomized couples to one of three interventions and used the gender of the index partner (i.e., the partner who reported drug use) as a blocking factor to ensure that the number of couples with substance use was balanced across the interventions (El-Bassel, Gilbert, et al., 2011). One partner was randomly designated as the index participant if both partners met substance use eligibility criteria (El-Bassel, Gilbert, et al., 2011).



**Table 2.** CONNECT 2 Wellness Promotion Intervention Components.

Risk Reduction Activity	Wellness Promotion Activity
<ol style="list-style-type: none"> <li>1. (i) Learned facts and myths about HIV and other STIs. (ii) Identified personal triggers and drug-related triggers for engaging in unprotected sex. (iii) Identified injection-related risk factors for HIV/AIDS and HCV. (iv) Identified personal values and positive reasons to stay healthy. (v) Identified and evaluated communication styles. (vi) Modeled and practiced speaker/listener techniques.</li> <li>2. (i) Learned effects of HIV and other STIs on couples. (ii) Identified how gender-related power imbalances affect sexual decision-making in couples. (iii) Learned safer sex practices in the context of a loving relationship. (iv) Learned the decision-making process (including HIV testing and monogamy). (v) Learned effects of drugs on sexual desire, performance, and dysfunction. (vi) Set a couple risk reduction goal.</li> <li>3. (i) Practiced communication in relationships - sexual and drug-related issues. (ii) Role-played and practiced speaker/listener technique. (iii) Discussed male and female anatomy. (iv) Learned male and female condom and lubricant use. (v) Identified a safer sex “menu.” (vi) Set couple risk reduction goal.</li> <li>4. (i) Learned the relationship between drug use and risk behavior for HIV infection. (ii) Identified triggers for drug use in general, and injection drug use. (iii) Demonstrated and practiced three cognitive skills to deal with drug-related triggers. (iv) Located needle exchange programs. (v) Modeled and demonstrated correct needle-cleaning procedures. (vi) Set couple risk reduction goal related to reduced or safer drug use.</li> <li>5. (i) Learned problem-solving related to HIV risk reduction. (ii) Practiced HIV testing with a partner as a prevention strategy and identified the optimal position on the safer sex hierarchy/continuum.</li> </ol>	<ol style="list-style-type: none"> <li>1. (i) Learned the importance of personal fitness, strength-building, flexibility, and aerobic exercise. (ii) Learned how to take their pulse and use a pedometer. (iii) Learned an aerobic exercise routine and set goals for fitness. (iv) Assessed current health risks, measured BMI, and constructed wellness-related goals.</li> <li>2. (i) Identified healthy and unhealthy food options. (ii) Set weekly goal and identified barriers and solutions to achieve this goal. (iii) Learned the relaxation technique “guided visual imagery” (GVI), a self-relaxation strategy that is grounded in mindfulness.</li> <li>3. (i) Learned about prevention strategies for common health concerns. (ii) Identified emergency vs. nonemergency medical concerns. (iii) Negotiated the healthcare system. (iv) Identified and mapped strategies for overcoming stigma associated with drug use. (v) Identified healthcare needs, barriers, and solutions.</li> <li>4. (i) Reinforced fitness goals. (ii) Introduced ten different strength-building exercises.</li> <li>5. (i) Learned effects of rest and relaxation on health (including the importance of sleep and relaxation on health and well-being). (ii) Identified personal health concerns. (iii) Developed goals to improve patterns of rest and relaxation. (iv) Practiced relaxation skills using the guided visual imagery technique.</li> </ol>

### Intervention

**CONNECT 2 Intervention Arms.** The intervention sessions were divided into three arms: (1) couple-focused wellness promotion, (2) couple-focused HIV/STI risk reduction, and (3) individual risk reduction. Risk reduction interventions have been previously described in another publication (El-Bassel, Gilbert, et al., 2011). Each arm consisted of seven weekly structured two-hour sessions delivered by a male or female facilitator who was matched to the gender of the index participant (El-Bassel, Gilbert, et al., 2011). All sessions were digitally audio-recorded to ensure that quality assurance (QA) procedures were met in all intervention sessions. In addition, the fidelity of implementation of all three conditions was recorded using session-specific QA checklists that were reviewed. Weekly corrective feedback was provided to facilitators when needed.

**CONNECT 2 Wellness Intervention.** The CONNECT 2 Wellness Intervention was guided by Social Cognitive Theory (Bandura, 1989; El-Bassel, Gilbert, et al., 2011), which has been applied to other wellness and health promotion interventions (“Eban health promotion intervention: conceptual basis

and procedures,” 2008; El-Bassel et al., 2016; El-Bassel, Gilbert, et al., 2011; El-Bassel, Gilbert, Terlikbayeva, et al., 2014; El-Bassel, Jemmott, et al., 2010; El-Bassel, Jemmott, et al., 2011; Heeren et al., 2018; Jemmott et al., 2011, 2019, 2021; Martinez et al., 2017; Tshenko et al., 2021). The components of the wellness promotion intervention focused on (1) maintaining a healthy diet; (2) promoting physical fitness in daily routines; (3) promoting age-appropriate recommendations for screening for common diseases such as cancers, heart disease, and diabetes; (4) improving access to healthcare services by identifying and addressing service barriers; and (5) learning stress-reduction exercises (see Table 2). Participants learned the importance of personal fitness, strength-building, and aerobic exercise, as well as how to check their pulse and how to use a pedometer. Participants also assessed and evaluated their current health risks and measured their body mass index (BMI). They were also taught about nutrition and meal planning, including identifying healthy and unhealthy food options. Participants learned about prevention strategies for common health concerns, identifying emergency versus non-emergency medical concerns, navigating the healthcare system when looking for a doctor and medical

insurance, preparing to see a doctor, and what they should expect from a doctor. Participants identified any stigmas associated with being a current or recovering drug user and mapped strategies for overcoming the stigma. Finally, participants identified their healthcare needs, barriers, and solutions, and learned about the effects of rest and relaxation on health, including the importance of sleep and relaxation on health and well-being. In the last session, participants wrote letters to themselves to remind them of future goals and progress throughout the intervention and had a graduation ceremony.

The CONNECT 2 Wellness Intervention differed from the HIV risk reduction intervention parent intervention by focusing on improving non-HIV health outcomes by using brainstorming, games, videos, experiential exercises, discussions, and skill-building activities to increase self-efficacy, outcome expectancy, behavioral skills, and wellness knowledge. However, both interventions consisted of five weekly structured two-hour sessions delivered by facilitators. A total of 489 individuals were randomized across the three arms and 190 to the wellness promotion. Attendance and participation at intervention sessions for all three conditions were high (El-Bassel, Gilbert, et al., 2011). More details on participant recruitment and retention are described in a previous publication (El-Bassel, Gilbert, et al., 2011).

## Measures

We conducted repeated assessments of sociodemographic and intervention-specific outcomes at baseline before the intervention, Immediate Post-Test (IPT), and at six months and 12 months post-intervention via Audio Computer-Assisted Self-Interviewing (ACASI) at a centrally located community research office. The ACASI enabled participants with low literacy to respond to questions by providing audio of the question and response options. Participants were reimbursed for completing assessments and intervention sessions.

Both Risk Reduction arms assessed outcomes related to substance use and HIV risk reduction. The Wellness arm assessed outcomes related to nutrition/diet, exercise/physical activity, engagement in health care, and ratings of participants' comfort with handling their medications, navigating stigma associated with drug use, and seeking medical care at baseline and all follow-ups; these outcomes constitute the focus of this paper and analyses presented herein.

Researchers collected data at baseline and all follow-ups on physical activity and eating behaviors in the past 90 days, including the number of fruits and vegetables consumed and the amount of physical activity performed. The National Cancer Institute's seven-item food frequency questionnaire assessed fruit and vegetable consumption (El-Bassel, Gilbert, et al., 2011). To assess physical activity, we used the CDC three-item questionnaire to measure physical activity and strength-building activities (El-Bassel, Gilbert, et al., 2011).

**Healthy versus Unhealthy Eating Habits.** To assess "Healthy versus Unhealthy Eating Habits," we used the seven

National Cancer Institute for five-a-day studies seven-item food frequency questionnaire to assess fruit and vegetable consumption (Thompson & Byers, 1994). This primary outcome was a binary variable that measured if participants met the five-a-day guideline of consuming five or more servings of fruits and vegetables daily in the previous 30 days. We also measured the number of daily servings of fruits, vegetables, and a combination, as well as daily consumption of fatty or fried food (eating and cooking with fat) in the previous 30 days.

**Exercise Habits.** We assessed physical activity with three items developed by the Centers for Disease Control and Prevention (2001), which assessed the number of days participants participated in at least 20 minutes of vigorous-intensity aerobic physical activity, strength-building activities, and moderate-intensity aerobic physical activity for at least 30 minutes. The primary outcome was a binary variable on whether participants engaged in strength-building activity on two or more days and engaged in at least four days or 30 minutes of moderate-intensity activity or 20 minutes of vigorous-intensity activity on at least five days (U.S. Department of Health and Human Services, 2008). Other outcomes included strength-building activities and the number of days of moderate or intensive cardiovascular activity over the previous seven days.

In addition, sociodemographic characteristics were collected, including gender, age, race/ethnicity, marital status, years of education, employment status, monthly income, history of homelessness, types of community correction settings in which they had enrolled in the past 90 days, and the number of times they were arrested or incarcerated.

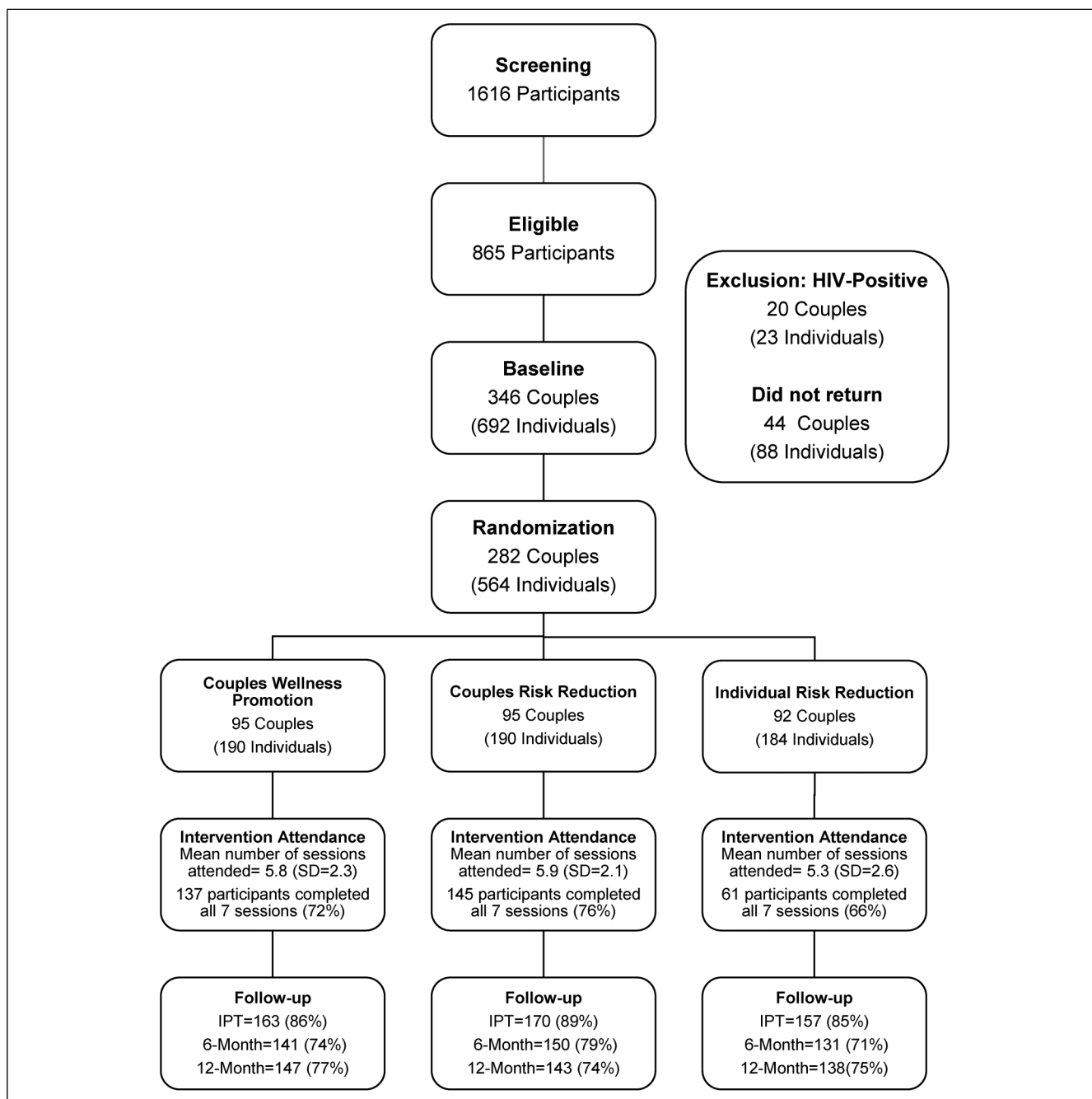
## Statistical Analysis

To test the hypotheses that wellness efficacy was increased, scores in healthy eating and exercise habits, and reductions in poor eating habits, multilevel linear models were used due to nonindependence in observations. Random effect parameters were included in the model to account for dependencies due to dyadic data and repeated measures. Each model included treatment assignment and follow-up time point and interaction terms between treatment assignment and time point, and also adjusted for gender and the baseline measures of the outcomes. The regression coefficient and its corresponding 95% confidence intervals (CIs) were reported as intervention effects for the total sample (i.e., couple wellness promotion vs. combined risk reduction [combining couple risk reduction and individual risk reduction]) and the subgroup analysis (i.e., couple wellness promotion vs. couple risk reduction) (Figure 1).

## Results

### Background Characteristics

The participants' sociodemographic characteristics, substance use, and criminal justice history are reported in Table 3. The



**Figure 1.** CONNECT 2 CONSORT form by intervention arm.

mean age of participants was 36.48 years ( $SD = 7.12$ ). Almost half ( $N = 268$ ; 47.60%) of participants identified as Black or African-American, 158 (28.06%) identified as Latino, and 65 (11.55%) identified as white. Close to half ( $N = 241$ , 42.81%) were married. Most of the sample ( $N = 357$ ; 63.41%) finished high school or higher education. The majority of the sample ( $N = 423$ ; 75.13%) participants were low-income, reporting less than \$400 in income a month, and 311 ( $N = 55.24%$ ) participants reported a history of homelessness. More than half

( $N = 326$ ; 57.90%) of the participants had been in prison or jail. Almost all ( $N = 542$ ; 96.2%) participants reported using illicit drugs in the past 30 days. No significant differences were found in any of the characteristics by study condition.

Figure 2 shows the means and 95% confidence intervals for eating habits and physical exercise at the baseline and each follow-up assessment by treatment assignments. Couple Wellness Promotion participants reported significantly more frequencies for exercise in the past 90 days than the

**Table 3.** Demographics, Reported Substance Use, HIV/STI Status, and Criminal Justice Involvement in the 30 Days Before Baseline.

	Total Sample (n = 563) <sup>b</sup>		Couple Wellness (n = 190)		Individual RR (n = 183) <sup>d</sup>		Couple RR (n = 190)	
Age (mean, SD)	36.5	7.1	37.0	6.8	36.3	7.2	36.1	7.4
Ethnicity								
Black/African-American	268	(48%)	94	(49%)	84	(46%)	90	(47%)
Hispanic/Latino	158	(28%)	51	(27%)	53	(29%)	54	(28%)
White	65	(12%)	24	(13%)	21	(11%)	20	(11%)
Married	241	(43%)	91	(48%)	78	(43%)	72	(38%)
Homeless <sup>a</sup>	311	(55%)	98	(52%)	104	(57%)	109	(57%)
Finished high school or higher education	357	(63%)	120	(63%)	116	(63%)	121	(64%)
Monthly income less than \$400	423	(75%)	149	(78%)	139	(76%)	135	(71%)
Substance use								
Binge drinking ever	314	(56%)	90	(47%)	108	(59%)	116	(61%)
Binge drinking in the past 30 days <sup>b</sup>	212	(38%)	61	(32%)	68	(37%)	83	(44%)
Illicit drug use ever	542	(96%)	181	(95%)	178	(97%)	183	(96%)
Illicit drug use in the past 30 days <sup>b</sup>	459	(82%)	154	(81%)	143	(78%)	162	(85%)
Cocaine use ever	469	(83%)	157	(83%)	159	(87%)	153	(81%)
Cocaine use in the past 30 days <sup>b</sup>	313	(56%)	102	(54%)	102	(56%)	109	(57%)
Crack use ever	389	(69%)	126	(66%)	131	(72%)	132	(69%)
Crack use in the past 30 days <sup>b</sup>	272	(48%)	86	(45%)	88	(48%)	98	(52%)
Heroin use ever	227	(40%)	98	(52%)	94	(51%)	85	(45%)
Heroin use in the past 30 days <sup>b</sup>	159	(28%)	55	(29%)	55	(30%)	49	(26%)
Marijuana use ever	396	(70%)	140	(74%)	129	(70%)	127	(67%)
Marijuana use in the past 30 days <sup>b</sup>	236	(42%)	79	(42%)	75	(41%)	82	(43%)
HIV seropositive <sup>c</sup>	3	(1%)	1	(1%)	1	(1%)	1	(1%)
Any STI <sup>c</sup>	23	(4%)	5	(3%)	5	(3%)	13	(7%)
Criminal justice involvement								
Ever been in a local jail	326	(58%)	117	(62%)	108	(59%)	101	(53%)

\*p < .05; \*\*p < .01.

<sup>a</sup>Homeless is defined as living in either a shelter or no regular place (park, street, subway, abandoned building).

<sup>b</sup>One or more days in the past 30 days.

<sup>c</sup>Self-reported.

<sup>d</sup>There was one missing case.



**Figure 2.** Summary of eating habits and exercise (frequency per month) at baseline, immediate post-intervention test (IPT), and 6- and 12-month follow-up assessments with 95% confidence intervals.

participants assigned to Couple Risk Reduction at IPT (23.1 [95% CI = 19.8, 26.4] vs. 15.8 [95% CI = 12.7, 18.9]) and 12-month follow-up (19.0 [95% CI = 15.5, 22.6] vs. 12.5 [95% CI = 9.6, 15.4]).

### Wellness Outcomes

Table 4 presents results from multilevel regression models for eating habits and physical activity outcomes for the

**Table 4.** Results from Multilevel Models for Eating Habits and Exercise (Frequency per Month) in the Past 90 Days: Effect Estimates, 95% Confidence Intervals, and *p*-Values.

Model		Entire Follow-up	IPT	6-Month	12-Month
Healthy eating habits	Full sample:	1.21	2.80	1.16	-0.49
	Couple wellness promotion vs. combined risk reduction	[-1.80, 4.21] ( <i>p</i> = .433)	[-1.79, 7.39] ( <i>p</i> = .232)	[-1.84, 4.16] ( <i>p</i> = .450)	[-5.30, 4.33] ( <i>p</i> = .843)
	Subgroup:	1.30	3.30	1.24	-0.82
	Couple wellness promotion vs. couple risk reduction	[-2.23, 4.83] ( <i>p</i> = .470)	[-2.09, 8.69] ( <i>p</i> = .230)	[-2.29, 4.77] ( <i>p</i> = .491)	[-6.51, 4.86] ( <i>p</i> = .777)
Unhealthy eating habits	Full sample:	-1.80*	-1.91	-1.79*	-1.67
	Couple wellness promotion vs. combined risk reduction	[-3.40, -0.10] ( <i>p</i> = .038)	[-4.51, 0.70] ( <i>p</i> = .152)	[-3.49, -0.09] ( <i>p</i> = .040)	[-4.40, 1.06] ( <i>p</i> = .231)
	Subgroup:	-1.89	-2.29	-1.87	-1.45
	Couple wellness promotion vs. couple risk reduction	[-3.88, 0.09] ( <i>p</i> = .062)	[-5.33, 0.75] ( <i>p</i> = .139)	[-3.86, 0.12] ( <i>p</i> = .065)	[-4.65, 1.75] ( <i>p</i> = .374)
Exercise habits	Full sample:	4.25**	5.50**	4.21**	2.93
	Couple wellness promotion vs. combined risk reduction	[2.00, 6.51] ( <i>p</i> < .001)	[2.06, 8.94] ( <i>p</i> = .002)	[1.97, 6.46] ( <i>p</i> < .001)	[-0.68, 6.54] ( <i>p</i> = .112)
	Subgroup:	5.50**	5.99**	5.49**	4.99*
	Couple wellness promotion vs. couple risk reduction	[2.98, 8.02] ( <i>p</i> < .001)	[2.14, 9.83] ( <i>p</i> = .002)	[2.97, 8.00] ( <i>p</i> < .001)	[0.93, 9.05] ( <i>p</i> = .016)

\**p* < .05; \*\**p* < .01.

total sample that compares couple wellness promotion versus Combined Risk Reduction (combining Couple Risk Reduction and Individual Risk Reduction) and the subsample that compares couple Wellness Promotion versus couple Risk Reduction. Couple wellness promotion participants reported significantly lower frequencies of unhealthy eating habits than combined risk reduction participants during the entire follow-up period ( $b = -1.80$ , 95% CI =  $-3.40, -0.10$ ;  $p = .038$ ). Participants in couple wellness promotion also reported significantly more exercise per month than participants in combined risk reduction across the entire follow-up period ( $b = 4.25$ , 95% CI =  $2.00, 6.51$ ;  $p < .001$ ), at IPT ( $b = 5.50$ , 95% CI =  $2.06, 8.94$ ;  $p = .002$ ), and 6-month follow-up ( $b = 4.21$ , 95% CI =  $1.97, 6.46$ ;  $p < .001$ ). From the results of the subsample group analysis, participants in couple wellness promotion had significantly more exercise in the past 90 days than couple risk reduction participants over the entire follow-up period ( $b = 5.50$ , 95% CI =  $2.98, 8.02$ ;  $p < .001$ ), and also at IPT ( $b = 5.99$ , 95% CI =  $2.14, 9.83$ ;  $p = .002$ ), 6-month follow-up ( $b = 5.49$ , 95% CI =  $2.97, 8.00$ ;  $p < .001$ ) and 12-month follow-up assessment ( $b = 4.99$ , 95% CI =  $0.93, 9.05$ ;  $p = .016$ ).

## Discussion and Applications to Practice

These study findings advance the evidence base of couple wellness interventions and wellness interventions as active comparison conditions. To our knowledge, this is the first RCT to find significant effects of a couples' wellness promotion intervention for improving the frequency of physical

fitness as well as reducing the frequency of poor eating habits among low-income couples who use drugs. The high rates of poor nutrition and low physical activity at baseline underscore the critical need to focus on chronic disease prevention and treatment efforts among those impacted by HIV risk and substance use. This study addressed key priorities of the Healthy People 2030 strategy (Hasbrouck, 2021; Levine, 2021); the NIH *All of Us* initiative, including reducing chronic disease, mental illness, and health disparities (Jones-Schenk, 2019); intensifying prevention efforts in heavily at-risk populations in concentrated areas (Hasbrouck, 2021; Levine, 2021); and increasing access to a continuum of evidence-based chronic disease prevention and treatment services for low-income populations (Lazar & Davenport, 2018).

Overall, the CONNECT 2 couple wellness promotion intervention was more efficacious than the risk reduction interventions collectively at reducing unhealthy eating habits across the entire follow-up observations, as well as specifically at the six-month follow-up time point. The couple wellness promotion intervention was more efficacious than the risk reduction interventions collectively, as well as the couple risk-reduction specifically, at improving exercise habits across the entire follow-up observations, as well as specifically at the IPT and six-month follow-up time points. Altogether, the magnitude and consistency of findings across wellness behavior outcomes in this study promote confidence in the efficacy of this wellness promotion intervention, ultimately providing support for the couple wellness promotion intervention being able to improve self-reported wellness behaviors among low-income couples who use drugs.

CONNECT 2 wellness promotion results are consistent with EBAN and prior research that has used wellness promotion interventions as attention control conditions (El-Bassel, Jemmott, et al., 2010; Mott & Crawford, 2008; NIMH, 2008). Therefore, there are important implications for future research about how to advance the evidence base and scale up these wellness promotion interventions (e.g., hybrid type 1 and 2 implementation trials of evaluating these interventions in real-world settings). First, there is a need for future research to examine the impact of improved general health outcome attainment on risk behaviors such as substance use and HIV. Second, a greater examination of a couples-based wellness intervention's effects on reducing healthcare distrust, which was highlighted during the COVID-19 pandemic, may provide an opportunity to increase general engagement in care and prevention recommendations for communities of color. Interventions that aim to improve health need to include core components of strengths and resiliency, social support, community networks, and access to federally qualified health centers, local clinics, and faith-based organizations. These organizations may play a role in promoting wellness interventions among their congregants and communities among some racial minority groups. The role of faith-based organizations in this arena increased significantly during the COVID-19 pandemic, where we saw and still see faith-based organizations being a hub for vaccine distribution and COVID-19 testing sites (Evans et al., 2021; Levin et al., 2022; Thompson et al., 2021).

The challenges of engaging low-income communities of color who use drugs when conducting clinical research are complicated, and include medical mistrust, fear, cultural differences, extra costs, and lack of awareness or knowledge of clinical trials; further, research language often excludes minorities (Ard et al., 2003; 1996; Jaiswal & Halkitis, 2019; National Academies of Sciences, Engineering, and Medicine et al., 2016; Rivers et al., 2013; Thompson et al., 2021). Additionally, many communities do not want to be associated or labeled with particular problems like high HIV/STI rates or substance use problems. Despite these challenges, we found high retention rates among both studies described. Although there is limited literature to guide the implementation of wellness interventions as control conditions for RCTs with drug-involved populations, including couples, we anticipate that there will be growing attention to this matter in light of increasing awareness of national health disparities. Further research is needed to determine whether wellness interventions such as EBAN and CONNECT 2 enhance effective case management and social work practice, especially in nonclinical settings and settings with limited supervision.

Several study limitations must be considered when interpreting these results and justifying wellness interventions as control arms for future RCTs and social work interventions. First, while self-reported data introduces the risk of participants providing socially desirable responses, the use of ACASI may have reduced that risk to self-report validity.

Second, the effects we note are likely generalizable to a similarly vulnerable, substance-using, low-income population; however, participants who were motivated to receive study incentives may have been more likely to enroll in, and complete, study components. The small sample size prevents generalizing the findings to other people who use drugs.

The CONNECT 2 Wellness intervention controlled for Hawthorne effects (special attention and group interaction) which should be considered for future wellness intervention control conditions (Sedgwick & Greenwood, 2015). Lastly, the costs of funding wellness interventions as control arms need to be considered as a potential limitation. However, it is estimated that obesity costs between \$147 billion and \$210 billion a year in the United States, as well as loss of productivity due to illness and premature death (Faruque et al., 2019). Therefore, cost-effectiveness should be included in the outcomes of future wellness control interventions (Wang et al., 2011). Some researchers have been critical of Wellness interventions, specifically if they address the multiple challenges of research, including study design in relation to addressing the research question, how bias can be addressed in the control, and if they are feasible and ethical, as these need to be addressed to maximize validity in future research (Byrd-Bredbenner et al., 2017; Kinser & Robins, 2013; LaFave et al., 2019). Finally, the suggested intervention model was tested in one country and was tested on two minority groups (Black and Latinx). Therefore, to generalize the present study results, it would be essential to test the suggested bicultural model in social work with other ethnic minority, immigrant, and racial groups.

CONNECT 2's findings have important implications for implementing and disseminating general health information to this population, which may be integrated with HIV/STI risk reduction, substance use treatment, and even Covid-19 interventions. High rates of session attendance and retention at the 12-month follow-up may indicate high motivation among low-income, drug-involved couples to participate in wellness interventions.

Two primary conclusions emerge from our findings. First, a focus on wellness that had significant findings, comparable to that of the risk reduction intervention. This finding is relevant for public health interventions, especially for communities of color and underserved populations. Second, the couple-oriented intervention enjoyed sustained gains over the individual intervention, offering the potential for promoting resilience among couples during a time of prolonged duress such as substance abuse or during a pandemic (e.g., COVID-19). Please note that pandemic-related risk avoidance fatigue may blunt the effectiveness of risk reduction interventions even more than our findings suggest.

As the efficacy of couple-based wellness interventions continues to be solidified, we recommend that CONNECT 2's findings be used to improve health outcomes in low-income populations via the use of wellness interventions as control arms. These intervention strategies may be scaled

up to curb the continued increase in substance use, chronic disease, and HIV among low-income populations while offering sustained gains in health-promoting behaviors, including engagement and adherence to healthcare recommendations. In addition, these strategies are compatible with a range of substance use and harm reduction settings to reduce chronic disease and other poor health behaviors among low-income, urban neighborhoods whose residents are at risk for morbidity and premature mortality from chronic diseases. Given the disproportionate impact of the COVID-19 pandemic on marginalized populations, wellness interventions like CONNECT 2, which focuses on health research equipoise and is a practical strategy to address the under-representation of marginalized groups in RCTs, are sorely needed and will provide worthwhile evidence for researchers, practitioners, and policy-makers.

SIG leadership has worked with marginalized populations for over 30 years, so we hope this description of our positive outcomes and intervention core components of the CONNECT 2 and EBAN trials help social workers, and other researchers, consider and plan for similar interventions for future RCTs to evaluate social and behavioral interventions. Future studies need to examine more deeply the specific social determinants that cause poor outcomes OR are barriers to positive health outcomes including the many layers of structural and institutional racism. By doing so, wellness interventions have an opportunity to be a system change model that should utilize community-based participatory research strategies to target culturally tailored interventions to serve not only low-income marginalized populations. EBAN and CONNECT 2 prioritized community involvement in all study design and development components, and staff included high numbers of people of color from the community. This equity lens is key to engaging hard-to-reach populations for future research. These practices and partnerships can also help increase response to community needs, community trust, quality of intervention development, and testing and uptake of the interventions. Researchers should be encouraged to publish results of control arms, particularly wellness control arms, in academic and nonacademic literature. By publishing the results of wellness control arms, researchers may advance health equity in study design and the evidence base for wellness interventions as a replacement for TAU. Future research should also include a systematic review and meta-analysis assessing the impact of wellness control arms and look at the impact of these wellness control arms for future uptake/considerations and sustainability.

By replacing TAU for HIV/STI RCTs with wellness interventions, we hypothesize that medically underserved populations in the United States and those internationally impacted by chronic illness, substance use disorders, and COVID-19, will have increased access to care, social support, and improved health outcomes, which may not have otherwise been accessible to them. Thus, a call is needed to encourage

social work researchers to take the lead in developing and testing wellness interventions to improve health outcomes, to test the impact of different modalities for vulnerable populations aggressively, and measure the benefit to society.

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