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Using Behavioral Incentives to Promote Exercise Compliance in Women with
Cocaine Dependence

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of
Philosophy at Virginia Commonwealth University.

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Abstract

USING BEHAVIORAL INCENTIVES TO PROMOTE EXERCISE COMPLIANCE IN WOMEN WITH COCAINE DEPENDENCE

by Leila Z. Islam, M.S.

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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To date, low rates of patient compliance have made it impractical to study whether regular exercise can contribute to positive outcomes in women with substance use disorders (SUD). One robust strategy for promoting and maintaining behavior change is contingency management (CM). CM has been used successfully to reinforce drug abstinence, treatment attendance, and other pro-social behaviors. CM delivers incentives (prizes) contingent upon target behaviors, though can be expensive. To reduce costs, CM is often delivered with an escalating variable-ratio schedule, first tested by Petry and colleagues (2005).

As a Stage Ib behavioral therapies development project (Rounsaville et al., 2001), the primary aim of the present study was to test the use of behavioral incentives (BI) to promote regular physical activity in a residential SUD treatment setting with cocaine-dependent women. The target was physical activity, which was objectively defined at two levels: 30 minutes of treadmill walking at any pace and treadmill walking at moderate intensity. Specifically, a pilot RCT compared rates of physical activity over a six-week study period in a sample of $N = 17$ women with Cocaine Dependence. $N = 10$ were randomized to BI group and $n = 7$ were placed

in the control (C) group. All participants completed baseline assessment, attended a 45-minute health and fitness education class, and were scheduled in exercise sessions three days/week. Those randomized to BI, however, were eligible three days/week, to receive incentives for meeting the target behavior(s). Follow-up assessment occurred at 3-weeks and 6-weeks post-randomization (midpoint and end of intervention), and 4-weeks post-discharge from the residential program.

The primary outcome variables (percentage of sessions completed and total time spent in scheduled sessions) were used for effect size estimations, which were then used to perform power analyses so that sample size calculations could be estimated for the design of a Stage II RCT. A significant Group effect demonstrated that the BI group spent a significantly greater number of total minutes in scheduled exercise sessions than the C group. This dissertation provided benchmark data on the utility of BI for promoting physical activity for women with cocaine dependence. These promising findings support the use of BI procedures to promote exercise compliance, which will ultimately allow scientists to better develop SUD programs that directly utilize the mental and physical health benefits of physical activity.

Using Behavioral Incentives to Promote Exercise Compliance in Women with Cocaine Dependence

Cocaine Dependence is a chronic relapsing disorder that increases risks for a variety of medical and psychosocial comorbidities. Treatments for the disorder generally yield modest effects. Strategies for improving outcomes and preventing relapse are of critical importance, particularly in women. This is because women are particularly vulnerable to the consequences of cocaine dependence (Najavits & Lester, 2008). One promising therapeutic adjunct may be physical activity or exercise (Weinstock, Barry, & Petry, 2008). While physical activity has been associated with decreased craving and increased abstinence rates in cigarette smokers, few published studies have examined the effects of exercise on recovery from other drugs such as cocaine. One factor that has impeded such research has been low levels of patient compliance with exercise protocols (Blue & Black, 2005).

A robust strategy for promoting and maintaining behavior change is Behavioral Incentives (BI), a form of contingency management which delivers incentives contingent upon target behaviors such as cocaine abstinence, treatment attendance, and other pro-social behaviors (Higgins et al., 1994; Kirby, Marlowe, Festinger, Lamb, & Platt, 1998; Svikis, Silverman, Haug, Stitzer, & Keyser-Marcus, 1997). In such early studies, repeated instances of consistently meeting the target behavior were rewarded using an escalating voucher schedule with a reset contingency. In this procedure, if a participant missed a target (e.g., had a lapse to drug use), then the value of the reinforcer substantially decreased to the baseline reinforcement level. While effective, using a continuous reinforcement schedule (i.e., rewarding every instance of the target behavior monetarily) that escalated resulted in considerable expense of up to \$1000 per participant when he/she was successful in sustaining behavior change (Higgins et al., 1994). To make BI more practical, Petry et al. (2000, 2005) developed a variable-ratio prize-incentive

method or the “fishbowl” method, in which variable magnitudes of reinforcement are delivered using an intermittent schedule of reinforcement with escalating reinforcers and at times, bonuses.

Specifically, to reduce the costs of classic BI escalating voucher reinforcement procedures, the fishbowl method literally used a “fishbowl” filled with small, medium, and large prize denominations to reinforce only a proportion of the target behaviors, and as the participant achieved longer periods of the target behavior, the number of prize drawings increased. With this approach, consistent performance of the target behavior resulted in an escalating number of prize draws. Some draws provided only verbal praise (e.g., good job!), hence consistent behavior was reinforced at a reduced cost. This balance of costs with positive outcomes led the Clinical Trials Network (CTN) to conduct a multi-site NIDA study using the Petry fishbowl method in “real life programs” with cocaine and other stimulant abusers. Ultimately, BI was named an evidence-based practice (EBP), as it was found to be effective in promoting treatment participation and retention in psychosocial programs (Petry et al., 2005).

Onken and colleagues (1997) developed the Stage Model of Behavioral Therapies to promote a rigorous scientific process that led from initial clinical innovation through efficacy research to ultimately effectiveness research (Stages I-III). This model was designed to reduce the burden on individual investigators caused by increasingly comprehensive methodological requirements expected when conducting clinical trials of behavioral treatments to secure funding (e.g. training manuals, training processes, process measures, preliminary findings). Rather, a Stage Model of Behavior Therapies recognizes the scientific merit of treatment development and initial evaluation activities, designated as Stage I, and not only large-scale RCTs. Stage I activities range, and include pilot and feasibility testing, manual writing, identification of target population, training program development, and procedures for supervising and monitoring

performance for new treatments. Stage I also uses basic behavioral research in the development of new behavioral treatments, to both understand the behavioral change process and promote positive change. Stage I is comprised of two key phases of work, Stage Ia and Stage Ib. Stage Ia focuses on therapy development and manual writing, needs assessment surveys, instrument development, or the use of focus groups composed of the target population to provide feedback about the acceptability of proposed new interventions. Stage Ib focuses on pilot testing of final or nearly final interventions (Rounsaville, Carroll, & Onken, 2001).

This Stage Ib therapy development project adapts BI to target physical activity. The specific aims are to: a) Evaluate participant acceptance of BI procedures; b) Confirm reasonableness of recruitment procedures (e.g., ability to enroll participants at the projected rate); c) Examine feasibility of BI implementation and the ability to track the number of exercise sessions and time spent in treadmill walking for the BI and C groups; d) Monitor participant response to the BI and C conditions and the extent to which BI motivates women to engage in physical activity through treadmill walking; and e) Estimate the effect size likely to be obtained for the two primary outcome measures (i.e., percentage of treadmill sessions completed; total time treadmill walking over a six week period).

The goal of this research was to determine if BI's robust ability to promote positive behavior change in the treatment of substance use disorders (SUDs) could be modified to target physical activity, thereby promoting regular physical activity in a sample of cocaine dependent women. Using the behavioral therapies development procedures outlined by Rounsaville and colleagues (2001), this Stage Ib dissertation study sought to balance scientific rigor with practical issues (e.g., intervention costs). Petry variable-ratio schedule fishbowl reinforcement procedures were modified to focus on physical activity. Based on the literature and preliminary surveys

with program women, two target behaviors were chosen for reinforcement: Level 1 target behavior: 30 minutes of treadmill walking at any pace under research assistant (RA) observation; and Level 2 target behavior: treadmill walking at moderate intensity, as defined by the American College of Sports Medicine (ACSM; 2007, revised) and individually prescribed for each participant, under RA observation.

Following Stage Ib guidelines, a 2-group pilot RCT was conducted in a residential treatment program for cocaine dependent women. Study participants were randomly assigned to either an experimental (BI) or control (C) group. Prior to randomization, all women completed baseline assessment, followed by a 45-minute health and fitness (HF) education class. For the next six weeks, BI and C group women had equal daily access to on-site treadmills. In addition, those randomized to BI had the opportunity to earn incentives three days/week (18 times total) for 30 minutes of treadmill walking, using the Petry fishbowl reinforcement procedures. They also had the opportunity to earn “bonus” draws for meeting moderate intensity exercise criteria. All treadmill walking was monitored and recorded for both BI and C group women. Primary outcome measures were a) the percentage of 30 minute treadmill sessions completed; and b) the total amount of time (minutes) spent treadmill walking. Follow-up assessments (including behavioral, physiological and psychological measures) occurred at study midpoint (3-weeks post-randomization), study completion (6-weeks post-randomization), and at study follow-up (4-weeks post-discharge from the residential program), and both BI and C group members were compensated equally for their time and effort for completing research assessments.

This Stage Ib therapy development pilot study aimed to provide data to inform effect size estimation in preparation of a subsequent Stage II large-scale RCT. Ultimately, this dissertation study sought to provide benchmark data on the utility of BI for promoting physical activity. If

promising, such procedures would allow scientists to better evaluate potential benefits of physical activity as an adjunct to treatment for women with Cocaine Dependence.

Review of the Literature

In 2003, over 35 million individuals 12 years and older in the United States (14.7% of the population) reported lifetime cocaine use (powder or crack) (SAMSHA, 2003). In 2007 an estimated 2.1 million Americans were using cocaine (SAMSHA, 2007) with the number of crack cocaine users estimated to be 610,000. A significant proportion (1.6 million) of these people also met DSM-IV criteria for current Cocaine Abuse/Dependence. Cocaine dependence, like other substance use disorders (SUDs), is a chronic relapsing disorder with adverse consequences that include criminality, loss of productivity, and a host of other morbidities (Hser, Huang, Brecht, & Evans, 2008). Additionally, chronic cocaine use increases the risks for medical sequelae such as cardiovascular effects (e.g., acute myocardial infarction and elevated blood pressure), central nervous system complications (e.g. stroke and seizures), and psychiatric disorders (e.g., agitation, anxiety, and severe depression) (Cregler, 1989; Lange & Hillis, 2001).

Most individuals with Cocaine Abuse/Dependence also use other drugs (Budney, Higgins, Hughes, & Bickel, 1993; Roll, Higgins, Budney, Bickel, & Badger, 1996). Among individuals reporting cocaine or crack as their primary drug of abuse, 70% reported using other drugs as well (Hull, May, Farrell-Moore, & Svikis, 2010). Among cocaine dependent women, the most common comorbid Abuse/Dependence categories include: Nicotine/Tobacco (Roll, Higgins, & Tidey, 1997), Alcohol (Carroll, Rounsaville, & Bryant, 1993; Higgins, Budney, Bickel, Foerg, & Badger, 1994), and Cannabis (SAMSHA, TEDS, 2007).

While historically, the majority of studies on cocaine and other SUDs focused primarily on men, more recent research focused on women. Some gender differences were found, with

more cocaine using women fulfilling DSM-IV-TR criteria for Cocaine Dependence compared to men (Compton, Cottler, Ben Abdallah, Phelps, Spitznagel, & Horton, 2000). Also, similar to patterns found for alcohol, women who use cocaine tend to progress from use to dependence at faster pace than men (Fattore, Altea, & Fratta, 2008). While findings are mixed, many studies have found that women with cocaine dependence experience more significant sequelae (family/social, medical, psychiatric) than men (Najavits & Lester, 2008). Women also have higher rates of psychiatric diagnoses and certain types of trauma, including more physical and sexual traumas, three times the rate of PTSD, and twice the rate of any anxiety disorder (Najavits & Lester, 2008). The data confirm that cocaine use in the U.S. poses a significant public health threat and may be particularly harmful to women. Not surprisingly, considerable effort has been focused on identifying effective cocaine dependence treatments in general, and also specific to women.

Existing treatments for cocaine dependence

Both pharmacological and behavioral interventions have been studied in the treatment of cocaine dependence. Pharmacologic treatments have included naltrexone (Schmitz et al., 2009), disulfiram (Sofuoglu & Sewall, 2009), antidepressants (i.e. bupropion) (Mooney et al., 2008), dopaminergic agents (i.e. haloperidol) (Amato, Minozzi, Pani, & Davoli, 2007), and GABA agents (i.e. topiramate) (Preti, 2007). These medications, primarily tested for their ability to provide symptomatic relief and encourage short-term cocaine abstinence, have yielded only modest effects at best when tested in RCTs (Karila, Gorelick, & Weinstein, 2008).

While behavioral interventions studied in the treatment of Cocaine Dependence have yielded more positive outcomes, overall effectiveness remains moderate. The most promising behavioral treatments include motivational interviewing (MI), cognitive behavioral therapy

(CBT), and behavioral incentives (BI). MI can improve patient engagement and early treatment retention (McKee et al., 2007). CBT produces positive outcomes with modest effect sizes (e.g., Korsten, 2002). BI, which targets drug abstinence, treatment attendance, and other pro-social behaviors had consistently yielded positive outcomes (Higgins et al., 1994; Jones, Huag, Stitzer, & Svikis, 2000; Kirby et al., 1998; Petry et al., 2005; Svikis et al., 1997).

Recently, efforts to combine such treatments to provide multimodal care have been launched and suggest that more intensive treatment programs may be more effective than single modality or less intense treatments (Knapp et al., 2009). Previous studies have found that adjuncts to drug treatment improved outcomes by 14-60% (Ball et al., 2007; Carroll et al., 2006). In the world of “real life” drug abuse treatment, promising outcomes when different treatment elements are combined has prompted efforts to enhance standard outpatient and residential programs with therapeutic adjuncts such as MI to promote treatment engagement and BI to improve treatment participation and retention (Petry et al., 2005). One promising adjunct that might contribute to positive outcomes in cocaine dependent women is physical activity or exercise (Weinstock et al., 2008).

Effects of physical activity in people with SUDs

To date, the majority of studies focused on the effects of exercise on substance use disorders have targeted tobacco users. In prospective clinical trials of tobacco dependent individuals, investigators found that exercise reduced both desire to smoke cigarettes and the severity of tobacco withdrawal symptoms while increasing rates of tobacco abstinence (e.g., Marcus, 1999, 2005; Martin, 1997; Prapavessis, 2007; Taylor, Houston-Miller, Haskell, & Debusk, 1988; Taylor & Katomeri, 2007; Taylor, Katomeri, & Ussher, 2005; Taylor, Ussher, & Faulkner 2006; Ussher, West, Doshi, & Sampuran, 2006). While more limited, the literature on

effects of exercise on people with other SUDs such as alcohol dependence and cannabis dependence has found that physical activity was associated with decreased stress (Sinha, 2007), improved affect (Palmer, Vacc, & Epstein, 1988; Sinyor, Brown, & Rostant, 1982) and decreased craving (Buchowski et al., 2011). The effects of exercise may go beyond mere drug abstinence: some former cocaine users reported that regular exercise was an effective relapse prevention strategy (Rohsenow, Martin, & Monti, 2005).

Recent studies have added to a growing body of literature examining the effects of various forms of exercise in people with SUDs. Dolezal and colleagues (2013) tested the efficacy of an eight-week endurance and strength training program in a sample of methamphetamine-dependent individuals in residential treatment. Study findings demonstrated improvements in aerobic exercise performance, muscle strength, and body composition in those randomized to the exercise training group compared to a group receiving only health education, supporting physiological changes that may aid the recovery process. Further, these findings supported the feasibility of implementing an exercise program into residential treatment (Dolezal et al., 2013). Trivedi and colleagues (2011) conducted a multi-site effectiveness study looking at adding exercise to treatment as usual in improving treatment outcomes. Specifically, it compares vigorous intensity high dose exercise to Health Education Intervention and targets stimulant abuse/dependence, though its findings are not yet published (Trivedi et al., 2011). Because physical activity has been associated with improved affect, drug abstinence, decreased craving, and relapse prevention in a variety of substance using populations, it may be a valuable adjunct to conventional treatments for cocaine dependence.

Level of physical activity required to produce beneficial effects

The majority of Americans are sedentary, so that any addition of physical activity provides physiologic benefits (www.cdc.org). Current recommendations state that sedentary individuals should increase their activity with moderate exercise and fewer exercise sessions, gradually increasing to 30 minutes/day for at least five days/week (A Report of the Surgeon General, 1996). Notably, women in the US have been shown to be less physically active than men (Troost, Owen, Bauman, Sallis, & Brown, 2002) making them an important target population.

In the field of addiction, the majority of studies focused on exercise as a treatment for SUDs have focused on nicotine dependence and smoking cessation. It is well known that initiating vigorous-intensity physical activity (usually defined as 60-80% of maximal oxygen uptake) in sedentary smokers motivated to stop smoking increases their chances of quitting by reducing nicotine withdrawal symptoms, negative moods, perceived stress, and weight gain (Daniel, Cropley, Ussher, & West, 2004; Taylor et al., 2005; Taylor et al., 2006; Ussher, 2008). However, initiating and maintaining vigorous-intensity physical activity is difficult for many smokers, and thus may be unrealistic. Moderate intensity exercise has also demonstrated a significant reduction in strength of desire to smoke, relative to baseline, when compared to light intensity exercise and no exercise (control) (Daniel et al., 2004). Relative to baseline, moderate intensity may result in significant reductions in restlessness, stress, tension and poor concentration post-exercise compared to light intensity exercise and control (Daniel et al., 2004).

In order to make exercise appealing for people with SUDs, it may be more appropriate to set lower, more realistic intensity targets. Walking is a moderate form of physical activity that delivers more oxygen to the brain than vigorous exercise (Ravaglia et al., 2008). Moreover,

walking on a treadmill has been used as the physical activity intervention in prospective studies examining the effects of exercise on smoking (Prapavessis, 2007; Taylor & Katomeri, 2007).

Thus, treadmill walking may be an ideal intervention for substance users because it is a moderate form of exercise that can be performed easily, allows monitoring of time, pace, and calories expended, and has been associated with positive outcomes.

Theoretical framework underlying the motivation to exercise

While it appears that exercise may have beneficial effects in the treatment of SUDs, the underlying mechanisms through which it may have an effect are not well understood. Self-determination theory (SDT; Deci & Ryan, 1985) provides a framework for conceptualizing and understanding the differential effects on treatment “success” (e.g., treatment compliance) that internal and external sources of motivation appear to have on the decision to participate in treatment and change behavior. The theory proposes that motivation can rise from a variety of different sources and that these sources will vary in their ability to influence lasting behavioral change. Specifically, behaviors that are perceived as being intrinsically motivated by the individual are more likely to be pursued than those deemed extrinsically motivated. However, to truly understand the effects of rewards, one must consider the interpretation, or functional significance, that the recipient is likely to give the rewards (Deci, 1971). SDT asserts that underlying intrinsic motivation is the psychological need for autonomy and competence. Thus, the effects of a tangible reward depend on how it affects perceived self-determination and perceived competence (Deci, Koestner, & Ryan, 1999). Ultimately, rewards can be interpreted by recipients primarily either as controllers of their behavior or as indicators of their competence. With the former view, rewards are predicted to prevent satisfaction of the need for autonomy and undermine intrinsic motivation. In the latter case, however, because rewards are positively

informational, they are predicted to provide satisfaction of the need for competence and thus to enhance intrinsic motivation (Deci et al., 1999). Finally, the informational aspect of positive feedback, or verbal rewards, generally leads to an enhancement of intrinsic motivation. This implies that some ways of offering and presenting rewards convey the task's importance for satisfying needs and wants, whereas other reward procedures impart the irrelevance of the task. For example, reward for meeting a specific performance standard (i.e. specific exercise targets) would convey competence, the importance of doing well, and the task giver's positive evaluation of the activity.

In most analyses of rewards, the effects of rewards are first broken into high- and low-interest tasks (e.g., Deci et al., 1999; Eisenberger, Pierce, & Cameron, 1999). When the tasks used in the studies are of low initial interest, rewards increase free-choice intrinsic motivation and leave task interest unaffected (Eisenberger et al., 1999). This finding indicates that rewards can be used to enhance time and performance on tasks that initially hold little enjoyment. As Bandura (1986) recognized, “Most of the things people enjoy doing for their own sake had little or no interest for them originally. . . . But with appropriate learning experiences, almost any activity . . . can be imbued with consuming significance.” This suggests that reward procedures are one way to cultivate interest in an activity (Cameron, Banko, & Pierce, 2001). Thus, rewards can be arranged to shape performance progressively to establish interest in activities (e.g. exercise) that lack initial interest (Bandura, 1986), and to maintain or enhance effort and persistence at a task (Eisenberger, 1992).

In the study, measures that may inform future research about potential mechanisms through which exercise may have an effect were collected. Specifically, assessment measures focused on the nature and severity of substance use (e.g. self-efficacy and motivation to change

substance use behavior, craving for drug), exercise history and beliefs (e.g., attitudes towards exercise, self-efficacy to exercise), and psychological correlates (e.g., mood, affect, and stress), and were assessed. In addition, practical issues such as barriers to exercise were measured, with a focus on environmental variables (e.g., availability of exercise equipment, personal safety). For example, I predicted following the health and fitness education class, control group participants would exercise. In line with SDT, their quantity of exercise was likely based on their level of autonomous motivation. The more the participants exercised and saw the benefit of exercise (e.g. reduction in depression and stress), the more likely they would be to increase their exercise to reach or continue the ACSM guidelines for moderate exercise. Furthermore, if an interest in exercise developed, the participants also would be more likely to maintain the behavior (captured in consecutive exercise sessions).

In contrast, the BI group likely initially exercised because of the external reward structure. Arguably, however, autonomous motivation may have also been attributed to attending the same health and fitness education class as the control group. Once participants began to feel the benefits of exercise (e.g. improved affect, decreased stress), they may have been more autonomous in their motivation to continue. Also, both groups may have realized that exercise lead to a reduction in craving, thereby also becoming a source of motivation to continue exercising to prevent consequences associated with relapse.

Limitations of physical activity as a treatment adjunct

To date, the primary impediment in the study of physical activity interventions is low levels of patient compliance with exercise protocols (Blue & Black, 2005). Indeed, low rates of exercise compliance have been observed in many studies of exercise in the treatment of nicotine dependence (Cornuz, 2007; Marcus et al., 1999). For example, in a study of vigorous exercise as

the intervention for 134 cigarette smokers, compliance issues were noted in nearly one-third of participants (32.7%; Marcus et al., 1999). Ussher and colleagues (2008) found that less than half of enrolled samples in their research were compliant with physical activity protocols, thereby limiting statistical power and raising issues of generalizability.

Low compliance rates with physical activity interventions may be of particular concern when the target population is women with cocaine dependence, especially those of low socioeconomic status. Such women face a number of barriers to achieving good health due to social determinants of health, which the World Health Organization defines as the conditions in which people are born, grow, live, work and age, including the health system (www.who.int). Social determinants influence health through individual and household circumstances, as well as concurrent environmental conditions that exist in areas where individuals live (Woolf et al., 2010). Therefore, individuals with good jobs, higher incomes, an advanced education, or historically favored racial or ethnic backgrounds experience better health not only because of these personal characteristics, but also because of their surroundings (Woolf et al., 2010). Importantly, access to safe neighborhoods, supermarkets with healthy foods, places to exercise, health care facilities, and clean air also affects health outcomes (Woolf et al., 2010). Further, an anonymous survey conducted several years ago with the target population identified practical barriers to regular exercise, including inability to access exercise equipment (i.e. treadmills) and lack of items essential if one is to engage in safe physical activity (i.e. tennis shoes, sports bras).

While patient compliance with physician-prescribed health behaviors (e.g., exercise, nutrition, medication) is an area of substantive public health concern (Eraker, Kirscht, & Becker, 1984), it has been particularly salient in the treatment of SUDs. Low rates of compliance have made it difficult (if not impossible) to evaluate whether such positive health behaviors may

contribute to more positive outcomes in the treatment of addiction. For example, in a study of 148 cocaine users, 42% demonstrated compliance issues with outpatient treatment (Haller et al., 1997). Due to a number of barriers, women with cocaine dependence may exhibit chronically poor rates of compliance with a host of behaviors, including with drug abuse treatment itself (Svikis et al., 1997). These barriers include concerns about childcare, transportation, social stigma, lack of awareness of the variety of treatment choices, problems with the confrontational models used by some SUD programs, and the time and economic costs of treatment (Copeland, 1997). Taken together, these data affirm that before potential benefits of physical activity on recovery from cocaine dependence can be evaluated, interventions to improve compliance with physical activity protocols must be developed.

Behavioral incentives to improve treatment compliance in people with SUDs

Behavioral incentives (BI) is a robust intervention that produce large and consistent (sustained) patterns of behavior change. BI has been used to promote compliance with a variety of target behaviors in persons with SUDs, such as cocaine abstinence (Higgins et al., 1994); treatment attendance (Svikis et al., 1997) and other pro-social behaviors (Kirby et al., 1998). Based on behavior modification principles, BIs reinforce desired behaviors by dispensing incentives (cash, vouchers, tokens, prizes) contingent upon verified performance of a target behavior (Petry & Stitzer, 2006). Three published meta-analyses to date have concluded that interventions with a single-drug target, especially opiates and cocaine, produce larger effect sizes, reduce all drug use, and increases clinic attendance than interventions that simultaneously target multiple drugs (Griffith et al., 2000; Lussier et al., 2006; Prendergast et al., 2006). However, some research has successfully targeted more than one drug simultaneously (e.g.,

Correia et al., 2003) or multiple behaviors other than drug use (e.g., Silverman et al., 2002; Wong et al., 2003).

In a hallmark study, Higgins et al. (1991) developed a voucher-based BI program for outpatient treatment of cocaine dependence. The target behavior was cocaine abstinence as measured by a negative urinalysis drug assay. All cocaine-dependent patients were treated with community reinforcement approach (CRA) therapy (Budney & Higgins 1998), an individualized intervention in which therapists go out into the community to engage patients in treatment and facilitate expansion of their nondrug-using networks. All patients left urine samples twice weekly, which were screened for the presence of cocaine. Half of the participants (N = 20) were randomly assigned to receive CRA alone, and the other half (N = 20) received CRA plus vouchers for every specimen that tested cocaine-negative. Voucher amounts escalated for each consecutive negative specimen, such that the first negative sample resulted in \$2.50 in vouchers, the next sample \$3.75, then \$5.00 and so on. Over a 12-week period, participants could earn about \$1000 if they provided all negative specimens. The vouchers could be spent upon retail goods and services that were consistent with a drug-negative lifestyle, and were typically used for gift certificates, clothing, or electronics.

Participants randomized to a voucher plus CRA therapy condition had higher rates of continuous cocaine abstinence and longer periods of retention compared to patients randomized to receive CRA alone (Higgins et al., 1994). Three-quarters (75%) of participants receiving BI completed the study, compared with 40% receiving CRA alone. Over half of those in the BI condition achieved at least two months of continuous cocaine abstinence versus only 15% in the non-BI condition. Subsequent studies have added to the overwhelming evidence that BI is useful

for promoting initiation of cocaine abstinence as well as continuous abstinence (Higgins et al., 1994; Kirby et al., 1999; Silverman et al., 1996).

Importantly, Higgins and colleagues (1994) demonstrated that the most efficacious method to promote and sustain abstinence from cocaine combined a progressively increasing, or escalating, magnitude of reinforcement with a reset contingency. The schedule specifies the delivery of reinforcers of increasing magnitude following consecutive instances of abstinence, the delivery of additional high-magnitude reinforcers following blocks of consecutive instances of abstinence, and a reset of reinforcer magnitude to a low level following instances of drug use (Higgins et al., 1994). In later studies, similar findings were demonstrated in a group of cigarette smokers (Roll & Higgins, 2000) and methamphetamine users (Roll et al., 2006).

The protection against relapse is quite likely accounted for by the greater monetary loss that accompanies an instance of drug use following a period of abstinence in the progressive magnitude with reset condition compared with the other schedule conditions. For example, in the Roll and Higgins study (2000) a participant who tested positive following six consecutive negative trials would forfeit, on their seventh trial, \$9.80 if reinforcement were scheduled with the fixed schedule, \$6.00 if reinforcement were scheduled with the escalating magnitude without the reset, and \$33.50 if reinforcement were scheduled with the escalating magnitude with a reset schedule. Additionally, with the reset procedure, participants would forfeit additional money by virtue of not being able to follow the prescribed escalation to its highest magnitudes. Instead, the individual would have to repeat the low magnitude portion of the progression, thereby potentially losing even more money (Roll & Higgins, 2000).

BI has also been used to target other treatment-promoting behaviors such as participation in individual and group drug treatment sessions (Jones, 2000; Rhodes, 2003; Svikis et al., 1997).

Rhodes et al. (2003) found that a prize-based BI program improved on-time counseling session attendance in methadone patients. Other such studies focused on women only. In a study of 85 cocaine dependent women, 60% of those randomized to the BI group displayed near perfect attendance in an intensive outpatient program compared to only 31% of those in the control (Jones et al. 2001).

Despite strong empirical support for BI in the treatment of SUDs, the translation of BI methods from research to clinical practice has historically been limited. A primary impediment to translating this proven methodology into clinical practice has been the cost of such programs, estimated to be about \$1,200 per person for a 12-week voucher-based BI program (Petry et al., 2007). Thus, to have practical applications for individuals with SUDs, strategies to reduce costs of BI are needed.

Development of cost-effective behavioral incentives

One method used to make BI more cost effective involves delivering reinforcement on a variable ratio schedule such that more costly rewards are provided less frequently. A variable ratio schedule for maintaining drug abstinence and promoting treatment retention was developed and empirically tested by Petry et al (2000). Using a lottery-based prize reward system, participants who continuously maintained drug abstinence earned the right to draw increasing numbers of tokens from a “fishbowl” containing hundreds of tokens. Each token in the fishbowl represented a reward ranging from a reinforcing message (“Good job”; 50% of tokens) to small prizes (snack; 41.8% of tokens) to large prizes (CD player; 8.0%) to a jumbo prize (stereo; 0.2% of tokens). The model also included an escalating voucher system, as the number of tokens that participants were able to draw from the fishbowl increased by one for each week that they remained drug abstinent as confirmed by urinalysis drug assays. If a participant tested positive

for drug use at any point in the study, the number of tokens he/she was eligible to receive that week was re-set to one. Results at four weeks showed that 39.7% participants assigned to the BI group were able to maintain continuous abstinence as compared to 21.0% of participants for whom no contingency was in effect ($p < 0.05$; Petry et al., 2005). The significantly higher rates of continuous abstinence for the BI group were also apparent at week 8 (26.3% vs 11.7%) and week 12 (18.7% vs 4.9%; Petry et al., 2005). On average, participants assigned to the BI group also remained in treatment for a significantly longer period of time than did the control group (8.0 weeks vs 6.9 weeks, $p < 0.02$). Most importantly, the mean per participant cost in this study was only \$203, which is one order of magnitude less than has been reported in studies of similar duration (Petry et al., 2007). Subsequent studies continue to highlight the potential of BI protocols that use variable ratio reinforcement schedules as a cost-effective method for maintaining abstinence in substance abusers (e.g., Olmstead & Petry, 2009). When the target behavior is drug abstinence, however, the social stigma of addiction often reduces enthusiasm for such procedures and encourages the study of BI with other, more health promoting behaviors

In summary, cocaine dependence is a significant public health problem, and women tend to experience greater physical and mental health consequences due to cocaine use than men. They have high rates of comorbidity. Overall, while effective treatments exist for cocaine dependence, they are modest at best. This suggests the need for treatment adjuncts to improve outcomes. One promising candidate is physical activity. To date, most studies focus on smoking cessation. They suggest that physical activity may enhance smoking cessation rates and reduce withdrawal symptoms. While many have posited that exercise may similarly contribute to positive treatment outcomes for persons with other SUDs, there is a paucity of empirical research in this area.

One factor that has impeded such research has been poor compliance with exercise protocols. When patients receive an insufficient “dose” of exercise, researchers cannot adequately evaluate whether regular physical activity can promote positive outcomes for persons with drug dependence. BI is a proven methodology that has been used to improve sustained adherence with a variety of behaviors, particularly drug abstinence. However, such methods have been proven to be costly to track and monitor, especially when each occurrence of a target behavior such as drug abstinence is rewarded (continuous reinforcement). Further, impediments to BI include philosophical differences (e.g., counselors feel extrinsic reinforcement undermines recovery; there is a general sense that drug users should not be rewarded for drug abstinence) and practical barriers (e.g., monetary costs of escalating incentives are prohibitive). The present study addresses some of these limitations and important barriers through a Stage I behavioral therapies development project that tests a BI intervention with a variable ratio reinforcement schedule designed to foster compliance with regular physical activity, not drug abstinence.

Stage Ia was conducted from 2011-2012 with funding from the VCU Institute for Women’s Health for a Community-Based Participatory Research project. The seed grant monies allowed the author of this proposal to modify the evidence-based practice of BI to target physical activity. Through conversations and surveys with Rubicon treatment program staff and patients and feedback from her mentoring team, the dissertation author operationally defined the Level 1 target behavior as 30 minutes of treadmill walking at any pace under research assistant (RA) observation, and identified the Level 2 target behavior as treadmill walking at moderate intensity, as defined by the American College of Sports Medicine (ACSM; 2007, revised) and individually prescribed for each participant, under RA observation. The Petry “fishbowl” variable ratio reinforcement schedule was adapted with prize magnitudes based on past

experience of the author's advisor's research team and program feedback. The primary aim of the dissertation project was to complete Stage Ib of intervention development using the template published by Rounsaville et al. (2001). Specifically, the pilot RCT allowed for comparison of women with cocaine dependence randomly assigned to either incentive (BI) or control (C) conditions for a six week period of time. Primary outcome variables for the RCT focused on exercise compliance and included: a) the total number of 30 minute treadmill sessions; and b) the total amount of time (minutes) spent treadmill walking over the six-week intervention period. The study focused on feasibility, refinement of assessment measures, and a comparison of outcome data at 6-weeks post-randomization. The latter allowed the dissertation author to estimate effect size in preparation for a Stage II RCT, in addition to providing benchmark data about the use of BI to promote compliance with exercise in a sample of cocaine dependent women.

Statement of the Problem

While physical activity has been associated with decreased craving and increased abstinence rates in smokers, few published studies have examined the effects of exercise on recovery from other drugs such as cocaine. One factor that has impeded such research has been low levels of patient compliance with exercise protocols. One robust strategy for promoting and maintaining behavior change is contingency management or Behavioral Incentives (BI). Using behavior modification, BI delivers incentives (prizes, vouchers) contingent upon target behaviors such as cocaine abstinence (Higgins et al., 1994), treatment attendance (Svikis et al., 1997), and other pro-social behaviors (Kirby et al., 1998). While the literature is replete with studies demonstrating the benefit of BI compared to control conditions (Stitzer & Petry, 2006) with an average effect size $d=0.42$ (Prendergast et al., 2006), the translation of BI methods from research

to clinical practice has met with some resistance. Contributing factors include philosophical differences (e.g., counselors feel extrinsic reinforcement undermines recovery) and practical barriers (e.g., monetary costs of incentives are prohibitive). The latter concern was addressed in part by Petry et al. (2005) who developed the “fishbowl” method, which uses escalating variable ratio procedures to reduce per participant costs of BI with similar effect sizes. However, impediments to implementation remain, as treatment programs continue to face difficulty financing a program that “rewards” individuals with SUDs for reaching the more socially-acceptable state of abstinence. Therefore, a BI program that targets physical activity in individuals with SUDs may reduce some barriers, as the focus becomes largely on general health improvements overall, while simultaneously addressing addiction problems.

As a Stage I behavioral therapies development grant (Rounsaville et al., 2001), the primary aim was to pilot test a BI intervention designed to promote regular physical activity in a sample of women in residential treatment for SUDs. The target behavior, physical activity, was objectively defined at two levels, as follows: the Level 1 target behavior being 30 minutes of treadmill walking at any pace under RA supervision and the Level 2 target behavior being treadmill walking at moderate intensity, as defined by ACSM (2007, revised) guidelines and individually prescribed for each participant, under RA observation. Specifically, the pilot RCT trial compared rates of physical activity over a six week study period in a sample of $N=17$ women with Cocaine Dependence. Participants completed baseline assessment, followed by random assignment to either the experimental (BI) or control (C) groups. All participants attended a 45-minute health and fitness (HF) education class, followed by equal daily access to on-site treadmills. Those randomized to BI, however, were also eligible three days/week to receive incentives for completing 30 minutes of observed treadmill walking during a scheduled

exercise session. Women assigned to the BI group received behavioral incentives (in the form of token draws for gift cards or prizes) for completing their scheduled exercise sessions (Level 1), and had the opportunity to earn “bonus” draws for meeting moderate intensity exercise criteria (Level 2). The number of draws a participant was entitled to make was determined by the frequency with which she attended her scheduled exercise sessions and completed 30 minutes of observed treadmill walking (Level 1). The number of draws increased by one token draw each time the participants met the target behavior. The more often she consecutively attended and exercised for 30 minutes, the greater the number of draws she was entitled to make from the fishbowl and the greater her chances were of winning a jumbo prize. If an exercise session was refused or missed, the next scheduled exercise session attended resulted in a reset to baseline, or one draw from the fishbowl. In addition, to reward moderate intensity exercise, beginning at week two each time a participant engaged in moderate intensity exercise during her scheduled exercise session (Level 2), she received a bonus draw (N = 1, in addition to drawing based on her number of attended exercise sessions. Behavioral incentives were dispensed by the research assistant (RA) monitoring the exercise sessions at the end of each exercise session through the use of a fishbowl (token draws) system (Petry, 2005).

All treadmill walking was monitored and recorded for both BI and C group women. Participants in both conditions were equally encouraged to attend their scheduled exercise sessions, engage in moderate intensity treadmill walking, and complete additional unscheduled exercise sessions throughout the week. Follow-ups occurred at study midpoint (3-weeks post-randomization), study completion and (6-weeks post-randomization), and study follow-up (4-weeks post-discharge from the residential program). Assessments were used to assess drug craving, mood, stress, motivation/self-efficacy, and physical health and well-being.

The specific aims of the project were to: a) Evaluate participant acceptance of BI procedures; b) Confirm reasonableness of recruitment procedures (e.g., ability to enroll participants at the projected rate); c) Examine feasibility of BI implementation and the ability to track number of exercise sessions and time spent in treadmill walking for the BI and C groups; d) Monitor participant response to the BI and C conditions and the extent to which BI motivated women to engage in physical activity through treadmill walking; and e) Estimate the effect size likely to be obtained for the two primary outcome measures (i.e., percentage of 30 minute scheduled treadmill sessions completed over a six week period; total time treadmill walking during scheduled sessions over a six week period).

Statement of Hypotheses

Based on the literature and study aims, the following hypotheses were tested:

1. Participants in the BI treatment group will complete more scheduled treadmill sessions compared to the C group over the six week intervention period.
2. Participants in the BI treatment group will spend more total time (minutes) on the treadmill in scheduled sessions than those in the C group over the intervention period.
3. Participants in the BI treatment group will complete more consecutive exercise sessions (i.e. sustained exercise) compared to the C group over the six week intervention period.
4. Participants in the BI treatment group will complete more moderate intensity sessions compared to the C group over the six week intervention period.

In addition to the number of treadmill sessions and total time spent on the treadmill, the relationship between physical activity and several measures of mood, craving, and other benefits or barriers of exercise were studied. Specifically, exploratory analyses will also examine

whether higher levels of physical activity are associated with lower levels of stress, more positive mood states, and an improved sense of self-efficacy.

Method

Objectives of Study

The primary goal of this study was to pilot test a BI intervention designed to promote regular physical activity in a sample of cocaine dependent women at a residential treatment facility. This study was approved by Virginia Commonwealth University's Institutional Review Board under "Behavioral incentives to increase compliance in women with cocaine dependence," protocol number HM12840.

Study Site

Rubicon, Inc., a large non-profit organization located in Richmond, VA, provides treatment services to women with substance use disorders (SUDs) through its 58-bed residential program. Specific services at Rubicon include individual and group counseling, motivational enhancement therapy groups, and case management for such needs as housing, transportation, and childcare. Treatment is delivered through individual and group counseling services focused on topics such as relapse prevention, re-entry skills, health and wellness, relationship, anger and conflict management, leadership skills, domestic violence, sexual abuse, parenting, and acupuncture. Previous research demonstrated that Rubicon admitted approximately 16 new women/month into residential treatment and approximately 80% of these women (N=12/month) were approved for 60 days of residential care (Choi, Langhorst, Meshberg-Cohen, & Svikis, 2011; Meshberg-Cohen, Nilson, Suwal, Lee, & Svikis, 2009). Approximately 25% of the women were expected to not meet one or more of the inclusion criteria (e.g., fail to meet medical clearance, currently pregnant, fail to meet DSM IV criteria for cocaine dependence) and another

5% refuse study participation, yielding an expected final sample of N=8 women/month for study recruitment.

Experimental Overview

Using the Rounsaville et al. (2001) guidelines for therapies development (described below), the author of this dissertation completed Stage 1a therapy development activities, which were funded by the VCU Institute for Women's Health through a small grant focused on Community Based Participatory Research (CBPR). The study focused on the development of an interviewer-administered survey on exercise and exercise barriers, nutrition, and other correlates completed last year at Rubicon (Project O.P.E.R.A.: Opinions on Physical Activity, Exercise Barriers, Recovery, and Affect). The CBPR study engaged community drug abuse treatment staff and patients as well as researchers in the design of an intervention, and was used to select the target behaviors (30 minutes of treadmill walking and moderate intensity exercise), the schedule and magnitude of reinforcement for the proposed study, as well as other core intervention components. This dissertation study proceeded to Stage 1b, a pilot RCT. Stage 1a discussions and survey data collected with potential participants confirmed a strong interest in having an exercise program. Further, data collected identified practical barriers to exercise that potential participants faced, including the lack of footwear suitable for exercise.

Women enrolled in residential substance abuse treatment at Rubicon, Inc. were invited to participate in a RCT comparing behavioral incentives (BI) for physical activity to a control (C) group. The study involved baseline assessment, followed by scheduled exercise sessions three times/week over a six week intervention period. For the BI group, participants received incentives in the form of token draws for prizes for meeting targeted behaviors while the control group participants did not. Follow-up assessments occurred at study-midpoint (3 weeks post-

randomization), study completion (6 weeks post-randomization), and study follow-up (4 weeks post-discharge from the residential program) and focused on the nature and severity of substance use (e.g. self-efficacy and motivation to change substance use behavior, craving for drug), exercise (e.g., attitudes towards exercise), and other correlates (e.g., mood, affect, and stress).

At baseline, participants who provided informed consent completed questionnaires assessing demographic information, substance use history, self-efficacy and motivation to change substance use behavior, craving for drug, physical activity history, attitudes toward exercise, mood, perceived stress, and general health. Participants also had anthropometric measures taken (e.g., weight, waist-to-hip ratios) and underwent safety screening prior to beginning any exercise.

All women who consented to the study completed baseline assessment and attended a 45-minute health and fitness (HF) education class prior to randomization. After completing the HF class, participants were randomly assigned to either the BI or C group. Both groups were asked to schedule exercise sessions with a study research assistant (RA) and engage in 30 minutes of observed treadmill walking three times/week over the course of the six week study period. Both groups had the opportunity to engage in additional exercise sessions, which may or may not have been monitored. Both groups were provided with new athletic shoes, to ensure safe and effective exercising. Those in the BI group had the opportunity to earn incentives in the form of token draws for prizes for each instance of observed treadmill walking during a scheduled exercise sessions, while those in the control writing group did not have the opportunity to earn any incentives. At study mid-point (3 weeks post-randomization), study completion (6 weeks post-randomization), and study follow-up (4 weeks post-discharge from the residential program), participants were asked to complete a follow-up packet consisting of a selection of same

questionnaires administered at baseline and some additional questionnaires. Further, participants underwent urine drug screening at study completion and study follow-up.

Participants

Participants were recruited in-person by the principal investigator (PI) or RAs, who were unaffiliated with Rubicon's treatment. Women were approached within the first few days of residential treatment and asked to volunteer for a study in which they would be asked to walk on a treadmill.

Recruitment. Recruitment occurred at Rubicon, Inc., a residential women's substance abuse treatment facility, from July 26, 2012 through May 15, 2013. Study recruitment will continue until July 8, 2013, as to maximize the number of participants recruited into the study overall within the funding period. Recruitment procedures were based on those developed for three previous RCTs at Rubicon, which had proven to be effective in identifying women likely to meet study criteria. The PI or a RA worked closely with Rubicon intake staff to identify potential participants, using program admission records to identify residents who had recently been admitted for residential care and had a history of cocaine abuse or dependence. Once the PI or RAs identified a new admission potentially eligible to be in the study, the resident was asked to report to the Staff on Duty (SOD) office. Care was taken to minimize disruption to the resident's standard program activities. When the resident arrived at the SOD office, she was asked about her projected length of stay at Rubicon (which residents typically had a good sense of, and generally varied from 30 to 60 days, but could be extended if warranted). The resident was also confirmed to be 18 or older, not pregnant, and asked about recent substance use (past 30 days), regular lifetime cocaine use (i.e. ever having used cocaine regularly in her lifetime for 6 months at least 3 times/week), and her physical health and any major medical problems that

might preclude study participation. If the resident had been told that they would receive at least 60 days of residential care and met other inclusion criteria outlined in the screening, the PI or RA staff would tell her about the study in the on-site VCU Research Office, emphasizing the fact that their participation was voluntary and all study data would be kept confidential. Potential participants were told that they could receive up to \$85 in gift cards if they completed all research assessments. All were encouraged to ask questions and assured that a decision not to participate in the study would in no way affect their treatment at Rubicon. If the resident was interested in study participation, she was asked to sign a VCU IRB-approved consent form. The participant was provided a copy of the consent document (unless she declined), and the original consent form was retained by the research team and filed in a locked drawer. Dr. Dace Svikis, Professor of Psychology, Psychiatry, and Obstetrics and Gynecology at VCU, served as the research mentor and principal investigator identified on all IRB-related paperwork. She approved consent of all volunteers for the study per IRB research rules.

Inclusion criteria. To be included in the study, a woman had to: 1) Be at least 18 years of age; 2) Have ever used cocaine regularly in her lifetime (for 6 months at least 3 times/week); 3) Be approved for 60 days of residential treatment at Rubicon; 4) Received medical clearance from the Rubicon staff physician to participate in a regular exercise program; and 5) Be able to provide informed consent to study participation.

Exclusion criteria. Individuals were ineligible for study participation if they: 1) Were currently pregnant; or 2) Had an acute or chronic mental disorder or problems with literacy that would make them unable to provide informed consent or follow study protocol procedures (e.g., chronic psychosis, mental retardation, current suicidality).

Sample size. The sample size selected for the pilot study was not based on a standard power analysis (Cohen, 1988). Rather, recommendations from a seminal article describing procedures for a multi-stage model of intervention development was used, and allowed for an expected sample size of approximately 25 per group (experimental and control) (Rounsaville et al., 2001). Rounsaville et al. (2001) specifically noted that such studies should not be powered for statistical significance of group differences. Rather, they are meant to inform investigators about potential effect sizes so that more accurate power estimates can be made for subsequent RCTs of the intervention. Specifically, Stage 1a projects have included the initial use of focus groups composed of the target population to provide feedback about the potential feasibility and acceptability of the proposed new treatment methods, which in part was completed through the Institute for Women's Health study (Project O.P.E.R.A.). The typical specific aims of a Stage Ib project, such as the dissertation study, are to provide a strong test of a new treatment's efficacy, usually through a RCT. Stage Ib RCTs most typically are pilot studies with a nearly final version of the new treatment. For such pilot studies, the broad guideline that 15-30 subjects per cell are included is given (Rounsaville et al., 2001).

Study Procedures

Safety screening. In accordance with the American College of Sports Medicine (ACSM, 2007 revised) guidelines, study participants were required to have a protocol-defined negative stress test and completed safety screening measures prior to being cleared to participate in the study. Dr. Edmund Acevedo, Chair of the Department of Health and Human Performance at VCU, and a master's level graduate student RA from the same department, trained all RAs in the proper technique to measure blood pressure and heart rate for both data accuracy and participant safety, and consultation regarding such procedures was available throughout the study. In

addition, Rubicon has a standard practice of placing ill residents on “sanction,” requiring them to lie down in their rooms, and any participant who was confirmed to be on “sanction” was excused from her scheduled exercise sessions. Finally, all RAs involved in the conduct and monitoring of exercise sessions and related data collection and the PI were trained in Rubicon’s existing policies and procedures for management of acute psychiatric and medical symptoms that warranted immediate attention. While acute psychiatric and medical emergencies occur at relatively low rates at Rubicon, as a residential substance abuse program, it has standard operating procedures in place to manage such events. Treatment staff members are trained in crisis management procedures and study RAs were trained to work cooperatively with Rubicon counselors and staff who oversaw patient care, including on-site medical staff.

During the study, blood pressure and heart rate measures were taken prior to each supervised exercise session. Participants were evaluated prior to each scheduled exercise sessions to ensure that: a) at least one of three blood pressure readings was less than 160/100; and/or b) at least one of three heart rate readings was less than 100 beats/minute (bpm). If the participant had elevated blood pressure, per Rubicon’s standard operating procedures, she was placed on “sanction” by Rubicon staff and required to lie down to rest. If the participant’s heart rate was above 100 bpm, then her heart rate throughout the exercise sessions was continuously monitored with a Polar RS100 heart rate monitor. For unscheduled exercise sessions, study participants were educated on the importance of an active warm-up prior to beginning an exercise session and a cool-down/stretching exercise at the end of a session. Such activities were monitored during scheduled sessions and were encouraged during unscheduled additional exercise sessions to reduce risk of injury.

The following tests were completed prior to determining whether a woman was medically cleared for study participation (see Table 1 below):

Risk Stratification Form. The Risk Stratification Form is a standardized measure that aids medical staff in the assessment of participant safety prior to completing the Sub-Maximal Exercise Test. The inventory focuses on health and health behaviors (e.g., exercise, smoking, shortness of breath, and unexplained dizziness or fainting).

Sub-Maximal Exercise Test. The Sub-Maximal Exercise Test is a screener that evaluates cardiorespiratory fitness and rules out ischemic response to exercise, which has implications for cardiovascular disease. It was used to identify participants for whom exercise may be hazardous. It also informed the development of the participant's exercise plan (prescription), and provided data for the exercise prescription. A trained graduate student RA from the Department of Health and Human Performance processed the test data with a summary of: 1) participant's symptoms before, during, and after testing, 2) sub-maximal heart rate and percent of predicted maximal rate achieved, 3) time on treadmill and estimated maximal metabolic equivalent (METs) achieved, and 4) ECG summary. Any occurrence of symptoms that required the test be stopped (based on ACSM's Guidelines for Exercise Testing and Prescription) made the individual ineligible for study participation due to medical safety issues.

Physical Activity Readiness Questionnaire- Revised (PAR-Q; Canadian Society for Exercise Physiology, 2002). The PAR-Q is a 7-item questionnaire consisting of seven health-related items that determined if a woman requires additional consultation with the Rubicon physician before being cleared for study participation.

Baseline assessment. On the initial day of the study, participants were informed that the study involved a baseline assessment (expected to take two hours over one to two sessions),

followed by scheduled exercise sessions consisting of 30 minutes of treadmill walking three times/week over the course of six weeks. They were told that there would also be a 3-week follow-up assessment, a 6-week follow-up assessment, and finally a 4-week post-discharge follow-up assessment. Participants were told that they could receive up to \$85 in gift cards if they completed all research assessments.

The baseline assessment consisted of fifteen measures (see below) and were administered in a confidential setting by a RA or PI. Study participants were assured that the data they provided would not be shared with Rubicon clinical/treatment staff and that they would receive a \$30 gift card after finishing the baseline assessment battery.

Participants were asked to provide basic demographic and personal information. The following measures also were administered, including those assessing psychiatric diagnoses, the behavioral effects of exercise, motivation and self-efficacy regarding exercise and drug use, craving, mood and affect, the potential benefits of exercise, substance use, physical activity and physiological measurements (see Table 1 below):

Demographic Survey and Locator Form. Basic demographic data (age, race, education, marital status) was collected by a PI or RA. In addition, information about participant's whereabouts post-discharge from residential treatment was obtained to assist in locating the individual for final study follow-up. Specifically, participants were asked to provide the names, addresses and telephone number(s) for at least three people who were likely to know their whereabouts following treatment. They were assured that this information would be used only to contact participants to schedule the post-discharge follow-up visit. A similar form was used successfully in previous research studies at Rubicon. RAs only divulged that the participant

was participating in a research study. No information about drug abuse treatment was disclosed without written informed consent from a study participant.

Composite International Diagnostic Interview-Second Edition Alcohol and Substance Abuse Module (CIDI-2; Kessler et al., 1998). The CIDI was originally developed by the World Health Organization (Robins et al., 1988) to standardize the collection of psychiatric symptoms in its epidemiological studies, and then the Substance Abuse Module was modified and expanded (Cottler, 1991). The CIDI-2 (Kessler et al., 1998) is a fully structured, standardized instrument for assessment of substance abuse/dependence and other psychiatric disorders. It was developed for use in epidemiological studies and can be administered by trained lay interviewers who do not have a clinical background. It provides lifetime diagnoses (past and current) for substance use disorders according to DSM-IV and ICD-10 nosologies. The CIDI has demonstrated good reliability and validity for SUD diagnoses (Robins et al., 1989). The alcohol and drug use sections of the CIDI- 2 typically require 20–30 min to administer. The CIDI-2 Alcohol and Substance Module was administered at baseline only.

Addiction Severity Index (ASI). The ASI is a semi-structured interview that assesses psychosocial functioning in seven domains (medical, employment, alcohol, drugs, legal, family/social, and psychiatric). It has excellent reliability and validity and is often used to monitor change in each domain over time (McLellan et al., 1989). The ASI requires 45 minutes to administer and Dr. Svikis, trained and certified in ASI administration, completed all ASIs herself. The full ASI was administered at baseline only, and a modified version of the ASI (Alcohol/Drug and Psychiatric Module) was administered at study completion and study follow-up to measure change over time.

Exercise Benefits/Barriers Scale (EBBS; Sechrist, et al., 1987). The EBBS is used to determine perceptions of individuals concerning the benefits of and barriers to participating in exercise, using a Likert scale ranging from 1 to 4. The benefit component is comprised of 29 benefit items categorized into five subscales: life enhancement, physical performance, psychological outlook, social interaction, and preventative health. The barrier component includes 14 barrier items categorized into four subscales: exercise milieu, time expenditure, physical exertion, and family discouragement. Scores on the total instrument can range from 43 to 172. The higher the score, the more positively the individual perceives exercise. When the Benefits Scale is used alone, the score range is between 29 and 116. When the Barriers Scale is used alone, scores range between 14 and 56, and with this scale, the higher the score on the Barriers Scale, the greater the perception of barriers to exercise. Test-retest reliability was found to be .89 on the total instrument, .89 on the Benefits Scale and .77 on the Barriers Scale. The EBBS was administered at baseline, study completion, and study follow-up.

Exercise Confidence Scale (ECS; Sallis et al., 1988). The ECS is used to help demonstrate that an intervention produced a change in self efficacy for increasing physical activity. This survey is an abbreviated version of the Self-Efficacy and Exercise Habits Survey, and was designed to be more practical than the original, complete scales reported in Health Education Research. The survey yields two factors, “Sticking to it” and “Making time for exercise,” with higher numbers indicating greater confidence. The survey was administered at baseline, study completion, and study follow-up.

Motivation Measurement Scales (MMS; Ondersma et al.). The MMS was created due to psychometric limitations with existing measures of readiness to change. The MMS utilizes multiple visual analogue scale items tapping future use intention, avoidance efficacy, problem

recognition, and other key features of overall readiness to change. The 5-item measure has good internal consistency and will be asked about to cocaine use specifically. The MMS was administered at baseline, study mid-point, study completion, and study follow-up.

Cocaine Craving Scale-Brief (CCS; Tiffany et al., 1993; Sussner et al., 2006). The CCS is a 10-item questionnaire on cocaine craving with items focused on current craving. Each item is scored on a scale ranging from 1 for "Strongly Disagree" to 7 for "Strongly Agree." A total score is obtained by averaging all items, and higher scores indicate greater craving (Sussner et al., 2006). The scale has moderate to high reliability (Tiffany et al., 1993). The CCS was administered at baseline, study mid-point, study completion, and study follow-up.

Quick Inventory of Depressive Symptomatology – Self-Report (QIDS-SR₁₆; Rush et al. 2003). The QIDS-SR₁₆ is a 16-item version of the 30-item Inventory of Depressive Symptomatology (IDS) designed to assess severity of depression-specific symptoms. Scores range from 0 to 27 with higher scores representing greater severity of depressive symptoms. The internal consistency coefficient is high (Cronbach's alpha of 0.86). It has also been shown to have good inter-rater reliability with a kappa of .85 (Rush et al., 2008; Trivedi et al., 2004). The QIDS-SR₁₆ was administered at baseline, study completion, and study follow-up.

Life Stress Scale (LSS; Miller-Johnson, S., Sullivan, T.N., Simon, T.R., & Multisite Violence Prevention Project, 2004). The LSS is a 20-item scale that assesses specific life stressors that the participant may have experienced in the past year. For each life stressor, participants are asked to indicate if the stressor did not occur, occurred and caused minor stress, or occurred and caused major stress. The LSS was administered at baseline.

Snaith Hamilton Pleasure Scale (SHAPS; Snaith et al., 1995). The SHAPS is a 14-item scale that measures anhedonia, the inability to experience pleasure. The items cover the domains

of: social interaction, food and drink, sensory experiences, and interest/pastimes. Each item has four possible responses: strongly disagree, disagree, agree, strongly agree. The SHAPS was scored as the sum of the 14 items so that total scores ranged from 0 to 14, and a higher total score indicated higher levels of present state anhedonia. The SHAPS has adequate construct validity and satisfactory test-retest reliability (ICC = .70). (Franken et al., 2007). High internal consistency has also been reported (Cronbach's alpha of 0.94) (Franken et al, 2007). The SHAPS was administered at baseline, study completion, and study follow-up.

General Health Survey (based on SF-12v2; Ware et al., 1996). The General Health Survey was designed as a 12-item questionnaire to measure general health status from the patient's point of view. The survey included 8 concepts commonly represented in health surveys: physical functioning, role functioning physical, bodily pain, general health, vitality, social functioning, role functioning emotional, and mental health. Questions from the General Health Survey were administered at baseline, study completion, and study follow-up.

Timeline Followback for Alcohol and Drugs (TLFB; (Sobell & Sobell, 1992). The TLFB is a semi-structured, calendar-based interview that was originally developed to aid in the recall of past drinking behavior and has since been adapted for assessment of other drug use (cocaine) (Sobell & Sobell, 1996). Retrospective estimates of daily drug use over a specified period of time are recorded using memory aids to enhance recall. The TLFB has been shown to have high test-retest reliability (ICC values ranging from 0.70 to .94, with all $p < 0.001$) and good convergent and discriminate validity, (Fals-Stewart et al., 2000). The TLFB was administered at baseline and focused on the last 90 days, and at study follow-up and focused on the last four weeks.

International Physical Activity Questionnaire- Short (IPAQ-S; Craig et al, 2003). The IPAQ-S is a questionnaire that aimed to provide a common instrument that can be used to obtain internationally comparable data on health-related physical activity. The results of extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000 suggest that these measures have acceptable measurement properties for use in many settings and in different languages. Self-reported physical activity data were collected using the IPAQ-S, which asks participants to report activities performed for at least 10 minutes during the last seven days. Participants were asked to report time spent in physical activity performed across leisure time, work, domestic activities, and transport at each of three intensities: walking, moderate, and vigorous. Using the instrument's scoring protocol, total weekly physical activity was estimated by weighting time spent in each activity intensity with its estimated metabolic equivalent (MET) energy expenditure. One MET is defined as 1kcal/kg/hour, and is estimated to be equivalent to the amount of energy it takes to sit quietly. The IPAQ scoring protocol assigns the following MET values to walking, moderate, and vigorous intensity activity: 3.3 METs, 4.0 METs, and 8.0 METs, respectively. The IPAQ was administered at baseline, study mid-point, study completion and at study follow-up.

Rated Perceived Exertion (RPE; Borg et al., 1998). The RPE scale is used to measure the intensity of one's exercise. The RPE scale runs from 6 – 20. The numbers relate to phrases used to rate how easy or difficult a participant finds an activity. For example, 6 (no exertion at all) would be how a participant feels when sitting in a chair; 19 (maximal exertion) is extremely strenuous exercise level, and for most people this is the most strenuous exercise they have ever experienced. The RPE was administered once a week during a scheduled exercise session over

the course of the 6-week intervention period. Heart rate monitors were also used to measure changes in fitness levels, and recorded at baseline, study mid-point, and study completion.

Daily exercise log. Participants were asked to keep a daily exercise log to document their exercise, both scheduled and unscheduled, in addition to exercise they engaged in that does not involve the treadmill.

Anthropometric measures. Physical measurements including height, weight, calculation of body mass index (BMI), and waist circumference will be taken. Height, using a metric stick, and weight (lbs), using a calibrated scale, were measured for BMI (kg/m²) computation. Waist and hip circumferences were measured using a tape measure for determination of waist to hip ratio. Waist hip ratio was calculated by measuring the smallest circumference of the natural waist, usually just above the belly button, and dividing by the hip circumference at its widest part of the buttocks or hip. Anthropometric measures were taken at baseline, study mid-point, study completion, and study follow-up.

Table 1

Assessment Measures and Schedule

Measure	Assessment schedule			
	Baseline	Mid-point 3 weeks post- randomization	Completion 6 weeks post- randomization (end of RCT)	Follow-up 4 weeks post- discharge
Risk Stratification Form	x			
Sub-Maximal Exercise Test	x			
Physical Activity Readiness Questionnaire - Revised	x			
Demographic information	x			
Composite International Diagnosis Index	x			
Addiction Severity Index	x Full ASI		x *Alc/Drug Module Only	x *Alc/Drug Module Only
Exercise Benefits/Barriers Scale	x		x	x
Exercise Confidence Scale	x		x	x
Motivation Measurement Scales	x	x	x	x
Cocaine Craving Questionnaire	x		x	x
Quick Inventory of Depressive Symptomatology	x		x	x
Life Stress Scale	x			
Snaith Hamilton Pleasure Scale	x		x	x
General Health Survey	x		x	x
Timeline Followback for Alcohol and Drugs	x			x
International Physical Activity Questionnaire- Short	x	x	x	x
Anthropometric Measures (e.g. weight)	x	x	x	x
Urine Drug Toxicology			x	x

Health and fitness education class. All women who consent to the study attended a 45-minute health and fitness (HF) education class prior to randomization. The group was led by a graduate student from the Department of Health and Human Performance at VCU, the PI, or another trained RA. The HF class informed the women about the benefits of exercise and the

steps necessary for exercising safely and effectively while at Rubicon and thereafter (e.g., importance of warm-up and cool-down periods). RA's were trained in the core principles of the HF class and reminded women in both study conditions about safe exercise practices during subsequent individual exercise sessions.

Randomization. Those who qualified and consented to the study were randomized to either one of two conditions: control condition (no incentives) or a BI condition (incentives delivered using an escalating variable ratio reinforcement procedure with a reset contingency and bonuses). A randomization schedule was generated using a computer program, as recommended by a biostatistician, Dr. Leroy Thacker, prior to the start of the study, and women were randomized sequentially. Specifically, the randomization number for each participant was placed in an individual sealed envelope that was not opened until the participant had completed baseline assessments, safety screening, and attended the HF class. At that point, the participant was informed of her group assignment. The C group was referred to as the "Exercise Group" and the BI group as the "Exercise Plus Group." No stratification variables are proposed for Stage 1b pilot studies (see Rounsaville et al., 2001), but the two groups were compared on core baseline measures to check for differences that may have occurred by chance on important measures

Exercise procedures. The target behaviors selected for the six-week intervention were a) 30 minutes of treadmill walking three days per week at any intensity and b) treadmill walking at a moderate intensity. The study was designed specifically to reinforce a minimum duration of treadmill walking (30 minutes) without prescribing either a maximum duration or a specified level or intensity of exercise on one level, while encouraging moderate intensity exercise at another level. For example, the HF class informed women about moderate intensity exercise and

the benefits shown to be associated with such exercise. Taken together, the program allowed women to self-select the intensity of their exercise regimen with the opportunity to increase this level over time. To encourage an increase in exercise intensity, all participants were encouraged to meet the moderate intensity exercise criteria as defined by the ACSM guidelines once cleared for this level of exercise.

A required energy expenditure was not set as the primary criterion because some participants may not have been able to meet it, thus raising safety concerns, while others may have been constrained by it. For example, in a recent study on the effects of exercise as an adjunct to the treatment of depression, a dose of 16 kcal per kg per week (KKW) was selected based on public health recommendations and would require walking at an approximate pace of 4.0 mph for 210 minutes per week (Trivedi et al., 2011). However, some participants may not have been able to walk at such a pace or dedicate that amount of time to walking.

All women began in the Level 1 or self-paced exercise of 30 minutes of treadmill walking, and treadmill RAs tracked distance, pace, and incline from the treadmills. This decision was affirmed by Stage 1a anonymous survey data that found more than half (56.5%) of women had engaged in no exercise prior to entering Rubicon. Other options (e.g., aerobics classes, walking with a pedometer, sports) were considered but budget and time constraints made them too complex and reduced dissemination capabilities. Treadmill walking was able to be conveniently offered at Rubicon and required minimal space. The treadmills used (Landice L9 Club Pro Sport Trainer Treadmill) allowed RAs to objectively record and monitor start and stop times, distance walked during the time interval, pace, and incline. Further, treadmill walking was an activity that was not weather dependent and could be done in isolation (e.g., it did not

require bringing together a group of women, which could create problems if only one participant showed up).

After one week (or three consecutive uses of the treadmill), the woman's fitness was re-evaluated and participants were encouraged to engage in Level 2, or moderate intensity exercise. Moderate intensity exercise was calculated during the safety testing protocol for each participant, producing a heart rate range in bpm specific to each woman (e.g. 114-132 bpm for Participant X). Heart rate was monitored throughout each scheduled exercise sessions using a heart rate monitor (Polar RS100). Moderate intensity exercise was also determined using the Rated Perceived Exertion (RPE; Borg et al., 1998) scale and the "Talk Test," or commonly accepted definition of having a participant be able to speak, but not sing (as defined during HF class). As the participants increased their fitness levels, it was expected that they would be able to meet ACSM recommended guidelines for moderate activity. RAs were present at each scheduled exercise session to help determine and document engagement in moderate intensity exercise. Given that many of the women reported never exercising and/or no experience with a treadmill prior to treatment, ACSM guidelines were followed to ensure maximum safety, while still assisting women to achieve health benefiting workouts. Dr. Acevedo and the RA affiliated with the Health and Human Performance department were regularly consulted to help define walking at a moderate intensity for each participant.

All participants had three core exercise sessions scheduled weekly for six weeks, with the opportunity to engage in additional exercise. Whenever possible, the same days of the week and time of day was scheduled (e.g., Monday, Wednesday, and Friday at 9- 9:30 AM,) for these sessions. Rules outlining parameters associated with attendance to or excused absences from scheduled exercise sessions were reviewed with each participant and posted, both for the

“Exercise” and “Exercise Plus” groups. RAs were present on-site and were trained in protocol procedures for scheduling, monitoring, and recording physical activity that occurs on the treadmills at Rubicon. Research staff obtained baseline measures (e.g., heart rate (HR), blood pressure (BP)) with ongoing monitoring throughout the treadmill session. Summary variables included time spent on the treadmill, pace, incline, and total distance traveled. In addition, time spent in moderate intensity physical activity was calculated. Missed exercise sessions were documented as well.

All participants also had the opportunity to use the treadmill on non-core days (up to four days of the week), at non-scheduled times, or exercise for longer periods of time. Participants were asked to record any additional exercise completed outside of scheduled exercise sessions in an Exercise Diary provided. In summary, all participants had access to two types of exercise sessions (core scheduled sessions 3x/week and additional sessions). Core scheduled sessions included a RA present to observe and record the exercise completed, while additional sessions had varying levels of data recording.

Treadmill Exercise Measures. Research staff obtained baseline measures (e.g., heart rate (HR), blood pressure (BP)) with ongoing monitoring throughout each scheduled treadmill session. Summary variables included time spent on the treadmill, pace, incline, and distance traveled. In addition, time spent in moderate intensity physical activity was documented. Treadmill exercise measures were tracked at each scheduled exercise session by a RA, and every attempt was made to encourage participants to document such measures for additional unscheduled sessions.

Behavioral incentives intervention. Participants assigned to the BI group had the opportunity to receive incentives for meeting the two target behaviors, as follows: Target

Behavior 1: 30 minutes of observed treadmill walking at any intensity; Target Behavior 2: treadmill walking at a moderate intensity, as prescribed for that individual. Participants who met Target Behavior 1, or engage in 30 minutes of observed treadmill walking, had the opportunity to draw tokens from a “fishbowl.” To keep with the theme of the study, a gym bag filled with marked ping pong balls was used instead of a fishbowl with tokens.

Every time a participant completed 30 minutes at a level, she received an escalating number of prize draws to reinforce consistent and sustained physical activity. If she completed less than 30 minutes total on the treadmill, she was not able to draw. Missed sessions or failure to complete 30 minutes of treadmill walking resulted in a reset of prize draws to baseline level. Escalation resumed from baseline (two draws) until the participant completed three consecutive sessions that met the completion of 30 minutes of exercise criteria. At that time, the number of draws returned to the level achieved prior to reset

Understanding that many of the participants may not have had the physical shape to immediately go into the recommended moderate level exercise recommended by ACSM, the study offered “bonus” draws for the Target Behavior 2 higher intensity exercise. Women completing moderate exercise up to three times a week could earn a “bonus” draw (N = 1) at each session to reinforce moderate physical activity. At this level, women were expected to be able to achieve health benefits from exercise. Dr. Acevedo and RA from HHP reviewed participants’ workout progress (based on BP, HR, time spent on treadmill) and approved a woman’s desire to complete higher intensity workouts as necessary.

Overall, the incentives were designed to reinforce women to consistently show up and complete 30 minutes of treadmill walking three times/week (Target Behavior 1), improve their physical fitness, and go on to engage in moderate intensity exercise (Target Behavior 2) for the

greater prize draws. However, a woman could have chosen to stay at Level 1 throughout the study, with the overarching goal of the intervention being to increase physical activity among women with SUD.

Introduction of the Prize Gym Bag. For women randomized to the BI group, prior to the first exercise session, a RA showed participants the prize gym bag and posted Prize Key, explaining that the gym bag contained balls with colored dots on them, with each colored dot signifying a different prize level, as described in Petry et al.'s work (2005). Prizes were stored in a Prize Cabinet housed in the research office, with each shelf of the cabinet corresponding to a specific prize level. Specifically, women were informed that the prize bag contained 500 balls. Half of the balls (N = 250) were marked with a purple dot and corresponded to receiving the verbal reinforcement "Good Job" from the RA, and was not associated with a monetary reward. Another 41.8% of the tickets (N=209) were marked with a green dot and was equivalent to a "Small Prize." If the participant drew one of these balls, she was able to select a small prize valued at approximately \$5 (e.g., toiletries, laundry detergent, feminine products). Another 8% of the prize gym bag tickets (N=40) were labeled with a blue dot and corresponded to a "Large Prize," allowing the participant to select a large prize with an approximate value of \$15 (e.g., jewelry, blanket, writing journal). Finally, 0.2% (N = 1) was marked with a red dot to signify the "Jumbo Prize," and if drawn, the participant was able to pick a prize valued at approximately \$100 (e.g., gift card, digital camera, portable digital music player). Women at Rubicon were surveyed in advance of study launch to select popular prizes for the prize gym bag, and surveyed throughout the study to ensure the prizes stocked in the cabinet remained incentivizing.

With this approach, the monetary value of incentives remained more modest and has more potential for translation to "real life" clinical settings. Additional exercise, while verbally

reinforced by RAs, did not result in additional monetary reinforcement. This minimized risks for developing an “exercise addiction,” which is thought to be a minimal risk, as studies of this model and its potential to develop pathological gambling in participants has not been supported by the data (Petry et al., 2005).

Control group. Much consideration was given to the development of the control group. A yoked control group would have allowed for the examination of outcomes and control for the beneficial effects of simply receiving monetary incentives. Such a group was not included because it would have increased the complexity of the study, and data from such projects to date have not yielded compelling results in support of this design (Higgins, 2000). Alternatively, offering exercise and health education groups where the beneficial effects of physical activity and healthy eating could be emphasized was considered. Such a group, however, would have created a greater “response burden” for the control group as compared to the incentive group. Furthermore, the logistics of coordinating such a group at dates and times convenient for multiple control group women raised concerns. Therefore, the study included a C group that had identical access to the treadmill equipment with equal opportunities to schedule sessions as BI women. They also received the same verbal encouragement to engage in exercise from the RAs, who were encouraged to treat all participants the same regardless of group assignment. Notably, the HF class gave participants in the C group the same guidelines recommending that they walk for a minimum of 30 minutes three days/week. The only difference between the BI and C groups, therefore, was the receipt of incentives.

Study-Midpoint Assessments. Three weeks after randomization to a group, participants were asked to complete a follow-up assessment packet. Many of the same assessment given at baseline were administered, including the Motivation Measurement Scales,

International Physical Activity Questionnaire, and anthropometric measures. A new assessment at this time point included checking the daily exercise log (described below). The assessments were administered by the PI or RA and the participant received \$10 for her time and effort.

Study-Completion Assessments. Six weeks after randomization to a group, participants were asked to complete a follow-up assessment packet, including each questionnaire that was administered prior to the intervention except the demographic questionnaire, the CIDI, the full ASI, and the Life Stressors Scale. Additionally, participants were asked to continue to complete a daily exercise log and at this follow-up, participants were asked to undergo urine drug toxicology screening. The assessments were administered by the PI or RA and the participant received \$20 for her time and effort.

Study-Follow-up. Four weeks following discharge from the residential treatment program, participants were asked to complete a follow-up assessment packet. The packet included each questionnaire that was administered prior to the intervention except the demographic questionnaire, the CIDI, the full ASI, and the Life Stressors Scale. Additionally, participants were asked to submit their completed daily exercise logs and at this follow-up, participants were asked to undergo urine drug toxicology screening. The assessments were administered by the PI or the RA and the participant received \$25 for her time and effort.

Measures at Follow-Ups. As previously stated, many measures from the baseline assessment were included at follow-ups, with the exception of the demographic questionnaire, the CIDI, the full ASI, and the Life Stressors Scale (see Table 1 above). Throughout the intervention, participants were asked to complete a daily exercise log and at follow-ups, participants were asked to undergo urine drug toxicology screening.

Daily exercise log. Participants were provided with and asked to keep a daily exercise log to document their exercise, both scheduled and unscheduled, in addition to exercise in which they engaged that did not involve the treadmill. The exercise log was labeled as such, and included weekly calendar pages labeled to correspond with a participant's time in the study, with ample space to record exercise. The log also encouraged participants to track how she felt before and after she exercised.

Urine Drug Screen. An 8-panel urine drug screen that allows for on-site testing to assess for recent cocaine, heroin, sedative-hypnotics, marijuana/THC, benzodiazepines, amphetamines, methamphetamines, and other opiates was utilized at study completion and study follow-up.

Compensation. BI and C participants had the opportunity to earn equal amounts of compensation for their time and efforts for completing research assessments. All study participants received a \$30 gift card for the baseline assessment, a \$10 gift card for the 3-week mid-point assessment, a \$20 gift card for the 6-week end-point assessment, and \$25 for completing the follow-up assessment 4-weeks post discharge from the residential program. Thus, a woman who participated in all of the assessment visits earned the equivalent of \$85 in gift cards to a local merchant for her time and effort. Gift cards (i.e., Walmart gift cards) were selected because cash payment was not allowed by the study site. Further, gift cards have been described as “reinforcing” by women who participated in previous studies at Rubicon. In addition, women randomized to the BI group had the opportunity to win incentives, as described above.

Data Analysis Plan

Descriptive statistics were computed to examine participant characteristics. Independent t-tests and chi-square analyses examined whether there were significant differences between the

BI and C groups at baseline, study midpoint, and study completion. Paired t-tests and ML modeling were run to examine whether there were significant changes in variables over time.

To assess the effect of BI on exercise compliance, a Mixed Linear Model (MLM) (Searle, 1971; Wolfinger, 1992) for repeated measures was run for the outcome measures (i.e. percentage of 30 minute scheduled sessions completed over a six week period; total number of total minutes spent in scheduled sessions). MLM is the best choice to examine treatment-related changes in the context of missing data. MLM allows for the inclusion of both fixed and random effects, and allows for the complete analysis of repeated measures designs. Further, it is robust in the face of data “missing at random” (Little & Rubin, 1987) and could include relevant covariates.

Results

Flow of Participants through Study

A schematic summarizing the study design from study recruitment through the post-intervention assessment is shown in Figure 1. A total of $N = 26$ women provided informed consent. Of these, $n = 22$ completed baseline procedures, continued to meet inclusion/exclusion criteria, and were randomized to either the experimental or control groups. The other four women became ineligible for the following reasons: $n = 1$ discontinued due to multiple medical conditions and potential cognitive issues; $n = 1$ was unexpectedly discharged from SUD treatment within 24 hours of informed consent; $n = 1$ did not attend the HF class, which was required as part of baseline prior to random assignment (despite multiple efforts to schedule); and finally $n = 1$ elected to stop when she determined that she was no longer interested in exercising because she did not want to lose weight, and feared this would happen as part of the study.

Out of $n = 22$ participants who completed randomization, $n = 12$ (55%) were randomized to the behavioral incentives (BI) group and $n = 10$ (45%) were randomized to the control group (C). Of the $n = 22$ participants who were randomized, $n = 2$ were subsequently withdrawn from the study due to high blood pressure complications; $n = 1$ was discontinued related to a chronic pain condition; $n = 1$ was unexpectedly discharged from residential treatment (attending her first scheduled exercise sessions); and $n = 1$ withdrew herself from the study during Week 1 of the six-week intervention. Thus, the sample consisted of $N = 17$ women, with $n = 10$ (59%) in the BI group and $n = 7$ (41%) in the C group.

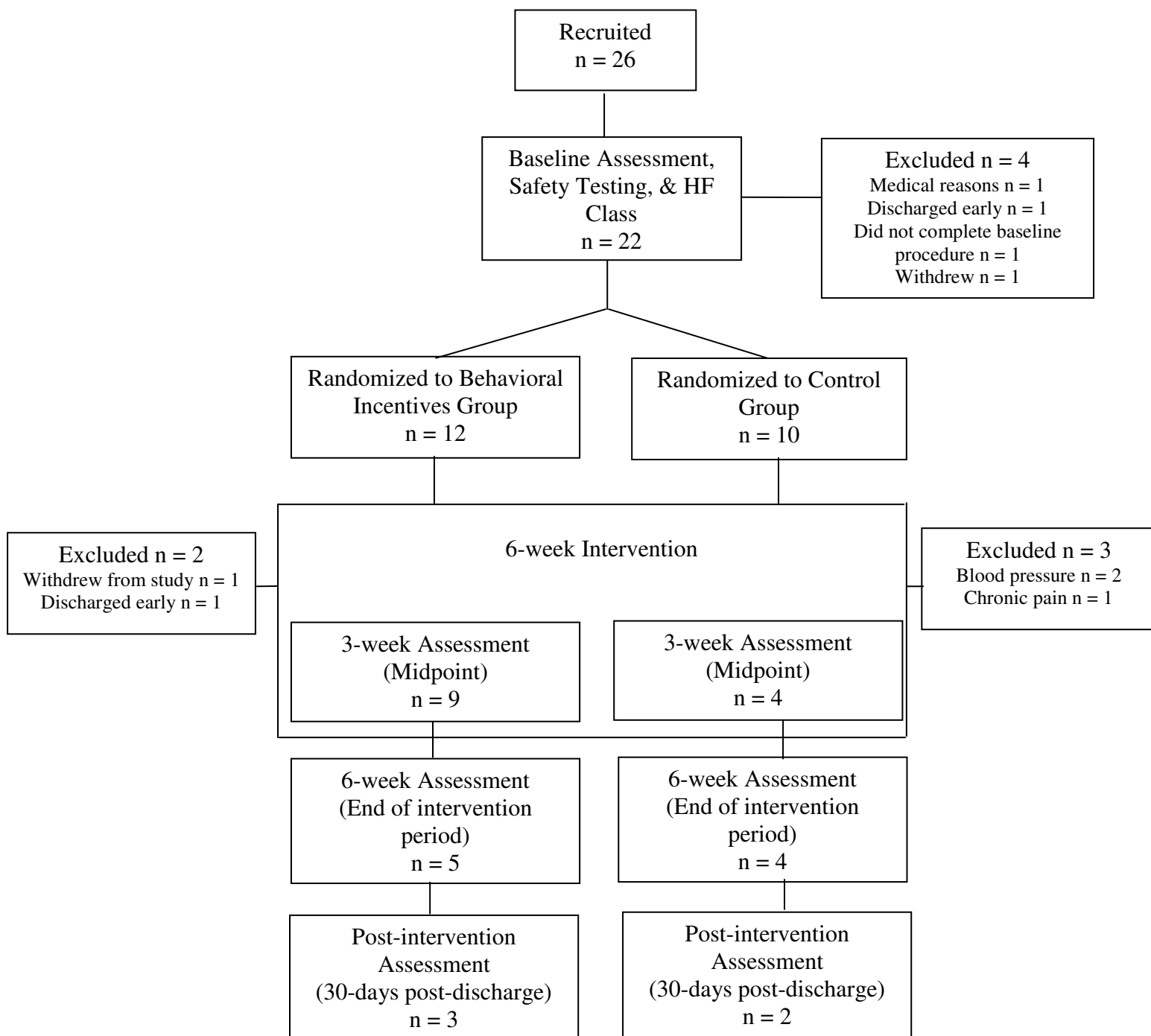


Figure 1. Flow chart of cohort through study.

Attrition from Study

As shown in Figure 1, an additional five of the 17 participants in the study left SUD treatment prior to the three-week midpoint assessment. Of these, $n = 2$ were from the BI group and $n = 3$ were from the C group. For two women from the BI group, $n = 1$ self-discharged after screening positive for illicit substances; her discharge was categorized by SUD treatment staff as “unauthorized” (i.e. against clinical advice). The second woman withdrew from the study during the first intervention week. For the C group, $n = 3$ were discharged early from SUD treatment (i.e., prior to their scheduled date), but were considered to have completed treatment successfully. Their departure was sudden and unexpected by the women themselves and our research staff. The end result was that $n = 13$ participants completed midpoint assessment, with $n = 9$ in the BI group and $n = 4$ in the C group.

Four participants from the study left Rubicon in the time period after the three-week midpoint assessment but prior to six-week (end of intervention) assessment, and all of them were from the BI group. Reasons for early discharge included: $n = 1$ left treatment against clinical staff advice; $n = 1$ was discharged early related to insurance problems; $n = 1$ was discharged early with her treatment considered incomplete; and $n = 1$ was discharged following arrest. This resulted in $n = 9$ participants who completed the six-week assessment, with $n = 5$ in the BI group and $n = 4$ in the C group.

Finally, for 30-day post-discharge from Rubicon assessment, $n = 5$ women participated in the assessment, including women $n = 3$ from the BI group and $n = 2$ from the C group. Research staff were unable to contact an additional $n = 3$ women for study follow-up. Also, two women (both from the BI group) had not reached the study follow-up time point when these

analyses were completed. Data from the 4-week post-discharge assessment were not analyzed given the extremely small sample size due to attrition.

Demographics

Table 2 summarizes demographic characteristics for the entire sample and separately for participants randomized to the BI and C groups. Overall, women were in their late-30's ($M = 38$ years, $SD = 10.1$); reported at least a high school education or obtained their GED ($M = 12.7$ years, $SD = 2.1$); were single/never married (64.7%); and identified their race as African-American (70.6%). While the majority of participants reported having one or more children (82.4%), nearly two-thirds (64.3%) of these women had no children currently living with them. When women randomized to either BI or and C groups were compared on these variables, using independent t-tests for continuous measures and chi-square analyses for categorical measures, no significant differences were found.

Table 2

Participant Characteristic

	BI ($n = 10$) % or $M (SD)$	C ($n = 7$) % or $M (SD)$	Total ($n = 17$) % or $M (SD)$
Age (years)	41.6 (9.8)	33.0 (8.9)	38.1 (10.1)
Education	13.2 (2.1)	12.0 (2.1)	12.7 (2.1)
Marital Status			
Single/Never Married	60.0 ($n=6$)	85.7 ($n=6$)	70.6 ($n=12$)
Married	20.0 ($n=2$)	0.0 ($n=0$)	11.8 ($n=2$)
Divorced/Separated	20.0 ($n=2$)	14.3 ($n=1$)	17.6 ($n=3$)

Race

African American	80.0 (n=8)	57.1 (n=4)	70.6 (n=12)
Caucasian	20.0 (n=2)	42.9 (n=3)	29.4 (n=5)

Note. BI = Behavioral Incentives; C = Control Group; Total = Total Sample

Compliance with Scheduled Exercise Sessions

Percentage of exercise sessions attended. The percentage of sessions (maximum 18) attended by BI and C women are shown in Figure 2. Given rates of attrition throughout the study, approximately half (52.9 %) of the participants remained in residential SUD treatment and had the opportunity to attend 18 scheduled exercise sessions if they chose to do so. Percentages were calculated to determine the number of scheduled exercise sessions completed out of the total number of sessions possible for each participant, given her time at Rubicon. Participants in the BI group completed on average 48.0% ($SD = 31.3$) of their scheduled 30-minute exercise sessions, as compared to 33.6 % for controls ($SD = 26.6$).

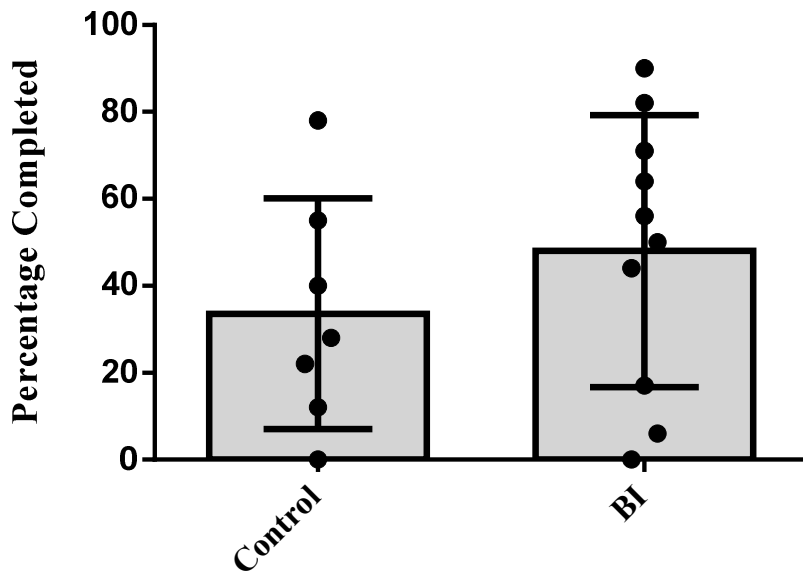


Figure 2. Percentage of 30-minute sessions completed by BI and control groups.

Minutes spent in exercise sessions. The total time that participants spent in scheduled sessions is shown in Figure 3. When a woman attended a scheduled session, she nearly always exercised for the full 30 minutes. On only four occasions did a participant exercise for less than the scheduled time. Further, participants who exercised did so at a moderate intensity. The total number of minutes spent exercising during the scheduled sessions was recorded, and compared between the groups. On average, participants in the BI group exercised a total of 208.0 minutes ($SD = 128.22$) while those in the C group exercised for 152.2 minutes ($SD = 133.06$).

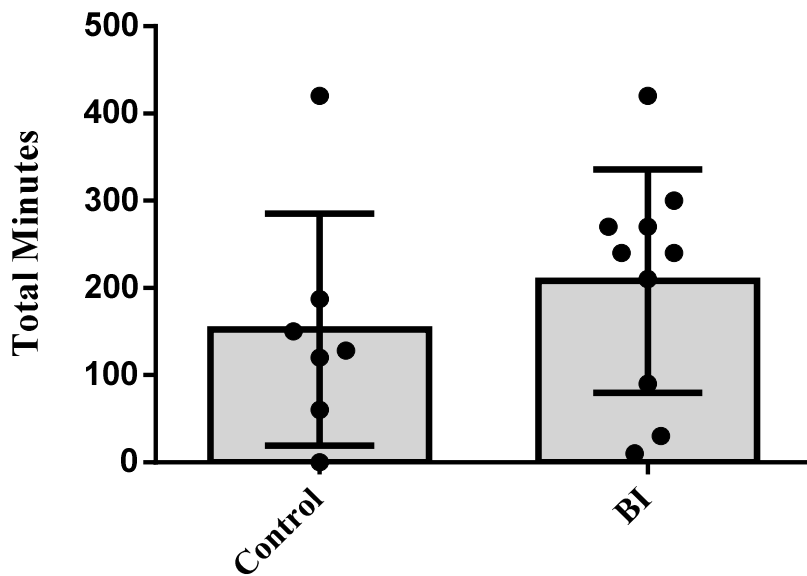


Figure 3. Total minutes spent exercising over six-week intervention period.

Compliance with Consecutive Scheduled Exercise Sessions.

The longest number of consecutive exercise sessions completed by each participant is summarized in Figure 4, which includes individual data points representing each participant for each group, the mean, standard deviation, and range of sessions for each group. Participants in the BI group completed a mean of 4.2 ($SD = 3.0$, range 0-9) consecutively scheduled 30-minute exercise sessions, compared to those in the control group ($M = 2.9$, $SD = 2.3$, range 0-6).

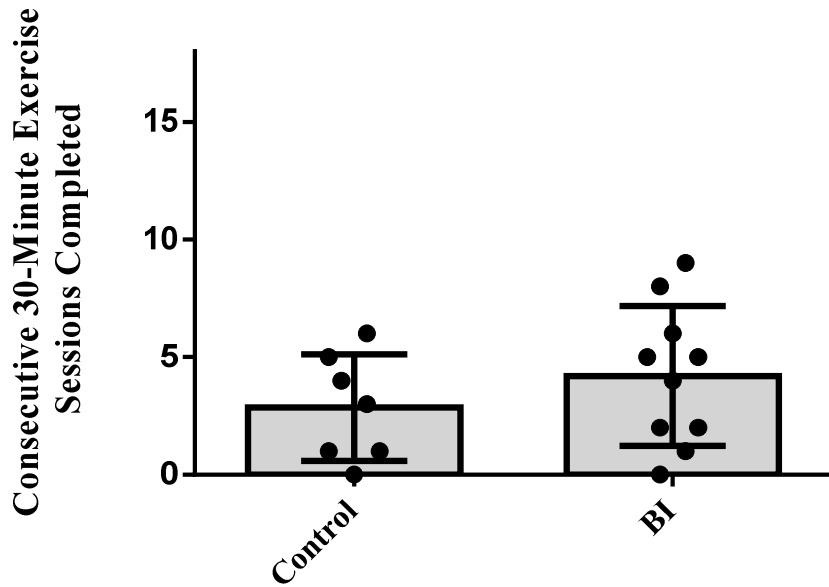


Figure 4. Longest number of consecutive 30-minute scheduled exercise sessions completed by group.

During the study, health and safety issues necessitated that the RA cancel or discontinue a session. This occurred with significant frequency, making it prudent to look not only at sessions completed, but also sessions attended. Figure 5 summarizes the individual data points representing each participant who attended consecutive scheduled exercise sessions, regardless of exercise session duration, in addition to the mean, standard deviation, and range of sessions attended. When number of consecutive treadmill sessions (any duration) attended were examined, participants in the BI group attended a mean of 4.9 ($SD = 2.8$, range 1-9) consecutive scheduled exercise sessions, compared to those in the control group ($M = 2.9$, $SD = 1.8$, range 1-6).

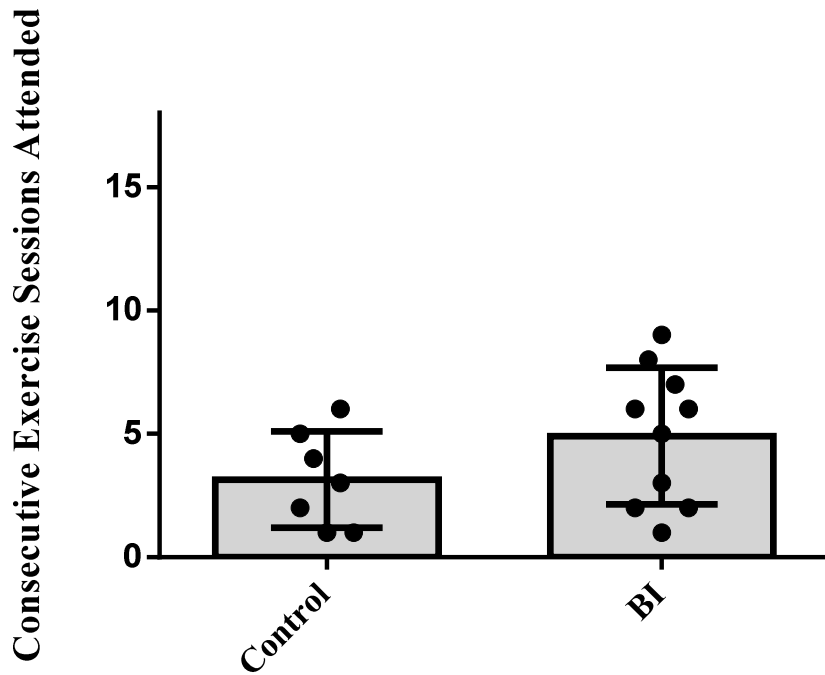


Figure 5. Longest number of consecutive scheduled exercise sessions (any length) attended.

During conduct of the study, it also became clear that SUD treatment responsibilities and other such factors at times necessitated cancellation or rescheduling of a session. Participants who were unable to attend a scheduled exercise session were asked to notify research staff. Reasons given by the women who notified staff they would be missing an upcoming session for failure to attend a scheduled exercise session included conflicting appointments for doctor's appointments or job interviews, being placed on sanction by Rubicon staff and/or nurse, or assignment of mandatory facility programs or duties (e.g. kitchen service). To examine the potential impact of such factors on outcomes, the longest number of consecutive exercise sessions accounted for was compared for BI and C participants. Figure 6 summarizes individual data points representing each participant, along with the means, standard deviations, and range of sessions, when 30 minute exercise sessions, exercise sessions of any duration, and excused

absences were combined. With these parameters in place, participants in the BI group presented with a mean of 7.9 ($SD = 4.4$, range 1-15) consecutive scheduled exercise sessions, compared to a mean of 5.4 for those in the control group ($SD = 5.3$, range 1-16). While in all three cases, the BI group mean was larger than the C group mean, independent samples t-tests showed no statistically significant differences between the groups when comparing the longest number of consecutive 30-minute sessions completed, the longest number of exercise sessions attended, or the longest number of consecutive scheduled exercise sessions accounted for, $p > .05$.

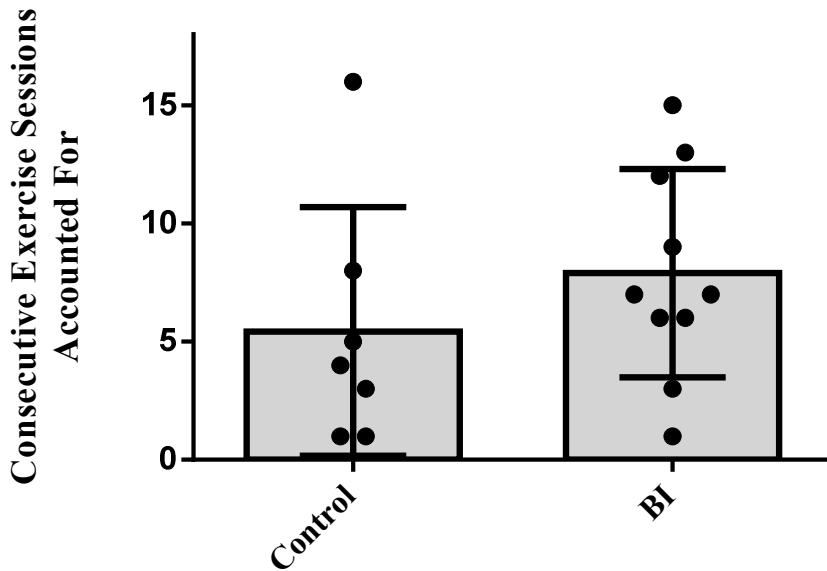


Figure 6. Longest number of consecutive scheduled exercise sessions accounted for.

Effect Size Estimation

The goal of a Stage 1b pilot RCT is to estimate the effect size of the primary outcome variables (Rounsaville et al., 2001). Effect size estimation was accomplished using two primary outcome measures over the six-week intervention period (i.e., percentage of 30 minute scheduled

sessions completed and total minutes spent exercising during scheduled periods). The means and standard deviations for the percentage of 30 minute sessions completed yielded a small to medium effect size ($r = .24$) and Cohen's $d = .51$. Similarly, the means and standard deviations for the total minutes spent exercising during scheduled sessions yielded a small to medium effect size ($r = .25$) and Cohen's $d = .51$. These estimated effect sizes were then used to perform power analyses and sample size calculations for the design of a larger clinical trial. It is estimated that a future RCT will need 70-90 participants per group for 80% power.

Difference between Behavioral Incentives and Control Group over Time

To assess the effect of BI on exercise compliance, Mixed Linear Models (MLM) (Searle, 1971; Wolfinger, 1992) for repeated measures was run for the outcome measures (percentage of 30-minute scheduled sessions completed over a six week period; total minutes spent in scheduled exercise sessions over a six week period). A MLM was attempted to be fit for the number of 30-minute scheduled exercise sessions completed using an identity covariance structure, which is the simplest of the structures and uses the least degrees of freedom. Even when testing only the intercept as random, the model could not converge, indicating that violations of the assumptions were likely too great. This was likely due in part to the lack of variation within the variables and small number of participants. A MLM was fit the outcome variable of total minutes spent in scheduled exercise sessions using a variety of variance-covariance matrices (compound symmetry, auto-regressive (homogeneous and heterogeneous) and diagonal); the results presented are from the models fit using a diagonal covariance structure.

The first ML model fit included one between subjects factor (Group: Control, Behavioral Incentives), one within subject factor (Time: 18 post-randomization exercise sessions), and the interaction between Group and Time. In the first model fit, the Group by Time interaction was

not significant ($p=0.841$) and thus was dropped from the model. The second ML model fit included the between subjects factor (Group) and the within subject factor (Time). In this model, there was a significant Group effect ($p=0.022$). The time effect, while not significant at the 0.05 level, was approaching significance ($p=0.059$). The significant Group effect demonstrated that the two groups (BI and C) differed in the total minutes spent in the scheduled exercise sessions. Specifically, the estimated marginal mean for the BI group was significantly greater than that of the control group ($M = 13.3 \pm 1.2$ versus $M = 9.2 \pm 1.4$, respectively).

Baseline Characteristics

To better characterize study participants, baseline characteristics were assessed using the CIDI-2, ASI, EBBS, ECS, MMC, CCQ, QIDS-SR, LSS, SHAPS, General Health Survey, TLFB, IPAQ-S, and anthropometric measurements.

Outliers, tests of normality, and recoding. Frequency distributions and univariate statistics were examined for evidence of non-normality and outliers. Outliers were thoroughly visually checked for collection or data entry errors, or recoded according to measure-specific protocol prior to being used in the analysis. Shapiro-Wilk statistics were used to test for normality of the data.

Primary drugs of dependence. Lifetime rates of DSM-IV-TR alcohol and other drug use disorders are summarized in Table 3. Findings are presented for each group and the total sample. As specified by the research protocol, all participants met DSM-IV-TR criteria for Cocaine Abuse/Dependence.

Table 3

DSM-IV Substance Use Disorder diagnosis (lifetime) for study participants

	BI (n = 10) %	C (n = 6) %	Total (n = 16) %
Alcohol Abuse	50.0 (n=5)	33.3 (n=2)	43.8 (n=7)
Alcohol Dependence*	0.0 (n=0)	66.7 (n=4)	25.0 (n=4)
Alcohol Abuse/Dependence	50.0 (n=5)	100.0 (n=6)	68.8 (n=11)
Cannabis Abuse	30.0 (n=3)	33.3 (n=2)	31.3 (n=5)
Cannabis Dependence	30.0 (n=3)	16.7 (n=1)	25.0 (n=4)
Cannabis Abuse/Dependence	60.0 (n=6)	50.0 (n=3)	56.3 (n=9)
Cocaine Abuse	10.0 (n=1)	0.0 (n=0)	6.3 (n=1)
Cocaine Dependence	90.0 (n=9)	100.0 (n=6)	93.8 (n=15)
Cocaine Abuse/Dependence	100.0 (n=10)	100.0 (n=6)	100.0 (n=16)
Opioid Abuse	10.0 (n=1)	16.7 (n=1)	12.5 (n=2)
Opioid Dependence	80.0 (n=8)	66.7 (n=4)	75.0 (n=12)
Opioid Abuse/Dependence	90.0 (n=9)	83.3 (n=5)	87.5 (n=14)
Sedative Abuse	20.0 (n=2)	50.0 (n=3)	31.3 (n=5)
Sedative Dependence	30.0 (n=3)	0.0 (n=0)	18.8 (n=3)
Sedative Abuse/Dependence	50.0 (n=5)	50.0 (n=3)	50.0 (n=8)

Note: One participant did not complete the CIDI; * = missing data for alcohol dependence criteria due to interviewer error

Current (past 12 months) substance use disorder diagnoses are summarized in Table 4. While all participants met criteria for Cocaine Abuse/Dependence as specified in the study protocol, over two-thirds of the sample (68.8%) met DSM-IV criteria for current Cocaine Abuse/Dependence. A large percentage of the women also met criteria for current Opioid Abuse/Dependence (70.6%). One-fourth of study participants met criteria for Alcohol Abuse (25%) in the last year, and no participants carried a current diagnosis of Cannabis Abuse/Dependence. BI and C participants did not differ in current or lifetime SUD diagnoses.

Table 4

DSM-IV Substance Use Disorder Diagnoses (current) for study participants

	BI (n = 10) %	C (n = 6) %	Total (n = 16) %
Alcohol Abuse	20.0 (n=2)	16.7 (n=1)	18.8 (n=3)
Alcohol Dependence*	11.0 (n=1)	0.0 (n=0)	6.7 (n=1)
Alcohol Abuse/Dependence	30.0 (n=3)	16.7 (n=1)	25.0 (n=4)
Cannabis Abuse	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Cannabis Dependence	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Cannabis Abuse/Dependence	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Cocaine Abuse	10.0 (n=1)	0.0 (n=0)	6.3 (n=1)
Cocaine Dependence	70.0 (n=7)	66.7 (n=4)	68.8 (n=11)
Cocaine Abuse/Dependence	80.0 (n=8)	66.7 (n=4)	75.0 (n=12)

Opioid Abuse	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	6.3 (<i>n</i> =1)
Opioid Dependence	70.0 (<i>n</i> =7)	66.7 (<i>n</i> =4)	68.8 (<i>n</i> =11)
Opioid Abuse/Dependence	80.0 (<i>n</i> =8)	66.7 (<i>n</i> =4)	75.0 (<i>n</i> =12)
Sedative Abuse	0.0 (<i>n</i> =0)	16.7 (<i>n</i> =1)	6.3 (<i>n</i> =1)
Sedative Dependence	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	6.3 (<i>n</i> =1)
Sedative Abuse/Dependence	10.0 (<i>n</i> =1)	16.7 (<i>n</i> =1)	12.5 (<i>n</i> =2)

Note: Current DSM-IV-TR diagnosis defined as if SUD criteria were met within the last year. One participant did not complete the CIDI; * = missing data for alcohol dependence criteria due to interviewer error

In order to further explore substance use, health, and psychosocial problems of study participants, a number of measures were examined. Tables 5 and 6 summarize anthropometric measures taken at baseline. General health status information is presented in Table 7, and levels of depression reported on the QIDS-16 are summarized in Table 8. Table 9 summarizes the following seven potential problem areas from the Addiction Severity Index (ASI): drug use, alcohol use, medical status, employment and support, legal status, family/social status, and psychiatric status.

Alcohol and drug history. Study participants reported drinking on average 2.9 days (*SD* = 6.9) in the 30 days prior to SUD treatment admission, and heavy drinking (three or more drinks/occasion) on 2.5 days of the 30 (*SD* = 6.9). Participants reported drinking regularly (three or more days/week) for 8.3 years (*SD* = 9.3) (lifetime), and drinking three or more drinks/occasion nearly all of those years (*M* = 8.1, *SD* = 9.4). Heroin and other opiates use was reported on 10.4 days (*SD* = 13.3) and 2.8 days (8.1) of the 30 days prior to treatment admission,

respectively. Lifetime use included 5.5 years ($SD = 6.3$) of heroin use and 2.6 years ($SD = 6.3$) of other opiate use. Cocaine was also used often in the days leading to treatment ($M = 9.0$ days, $SD = 12$), with lifetime use over 9.5 years ($SD = 6.2$). Most women chose to smoke cocaine (75%), though some used it intravenously (18.8%). Notably, all participants experienced reported problems with more than one drug (including alcohol). Specifically, over two-thirds (69%) were classified as having alcohol and other drugs problems, and nearly one-third (31%) had problems with two or more drugs (excluding alcohol). Most women (81.2%) had sought out treatment for drug use at least once previously, and those women had been in treatment on average 3.5 times ($SD = 2.2$, range: 1-8). Over a third of women (37.5%) had been in treatment for alcohol abuse, and on average had been treated 4.8 times ($SD = 2.9$, range: 1-8). At treatment entry, over half of the participants (56.3%) endorsed symptoms that were rated as indicating the need for additional alcohol treatment, and all participants (100%) were rated to need additional drug treatment.

Medical status. General health and medical history were assessed using the ASI, anthropometric measurements, and general health survey. Based on the ASI medical section, participants had an average of 2.25 ($SD = 2.8$, range: 0-11) overnight hospitalizations for medical issues. Over two-thirds of the women (68.6%) reported that they had one or more chronic medical illnesses, and a similar number (62.5%) stated they were prescribed medication(s) to treat their chronic medical problems. While no participants had a medical disability that qualified for support services, three participants (18.8%) reported experiencing medical problems every day for the 30 days prior to treatment enrollment. Based on this information, the interviewer felt over half (56.3%) of the women would benefit from additional medical care on admission to SUD treatment.

The Body Mass Index (BMI) data for study participants are shown in Table 5, with waist-to-hip ratio data shown in Table 6. Over one-third (37.5%) of participants had BMIs that were classified as in the obese or morbidly obese range. Analysis of height and weight data found the average BMI of participants to be in the overweight range ($M = 29.4$, $SD = 8.2$, range: 18-53), with an average waist-to-hip ratio in the moderate overall health risk range ($M = 0.76$, $SD = 0.12$, range: 0.43-0.88).

Table 5

Body mass index (BMI) at baseline

BMI Classification	BI (n=9) %	C (n=7) %	Total (n=16) %
Morbidly obese (35 or higher)	11.1 (n=1)	0.0 (n=0)	6.3 (n=1)
Obese (30 - 34.99)	33.3 (n=3)	28.6 (n=2)	31.2 (n=5)
Overweight (25 – 29.99)	22.2 (n=2)	42.9 (n=3)	31.2 (n=5)
Normal (18.5 – 24.99)	22.2 (n=2)	28.6 (n=2)	25.0 (n=4)
Underweight (18.5 or less)	0.0 (n=0)	14.3 (n=1)	6.3 (n=1)

Note. One participant from the BI group did not have a weight recorded.

Table 6

Waist-to-hip (WHR) ratio at baseline

Health Risk Based on WHR	BI (n = 9) %	C (n = 4) %	Total (n = 13) %
High (0.85 or higher)	11.1 (n=1)	25.0 (n=1)	15.4 (n=2)
Moderate (0.81 to 0.85)	22.2 (n=2)	0.0 (n=0)	15.4 (n=2)
Low (0.80 or below)	66.7 (n=6)	75.0 (n=3)	69.2 (n=9)

Note. Four participants did not have waist and hip measurements recorded.

General health ratings at baseline from questions from the general health survey are summarized in Table 7. Over half (52.9%) of participants rated their general physical health to be “Good” and nearly all women (94.1%) reported they were “Not limited at all” in completing moderate activities (e.g. moving a table, pushing a vacuum cleaner). Over three-fourths (76.5%) of participants felt that pain did not interfere at all with their normal work, while 17.6% of the sample stated that pain experienced interfered “Quite a bit” with their normal work. Nearly half the women (47.1%) reported that they had accomplished less than they would have liked in the past four weeks as a result of emotional problems, and 41.2% reported feeling downhearted and depressed “Some of the time.”

Table 7

General health status at baseline

	BI <i>n</i> = 10 %	C <i>n</i> = 7 %	Total <i>n</i> = 17 %
General health			
Excellent	20.0 (<i>n</i> =2)	14.3 (<i>n</i> =1)	17.6 (<i>n</i> =3)
Very good	20.0 (<i>n</i> =2)	28.6 (<i>n</i> =2)	23.5 (<i>n</i> =4)
Good	60.0 (<i>n</i> =6)	42.9 (<i>n</i> =3)	52.9 (<i>n</i> =9)
Fair	0.0 (<i>n</i> =0)	14.3 (<i>n</i> =1)	5.9 (<i>n</i> =1)
Moderate activities			
Yes, limited a little	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
No, not limited at all	90.0 (<i>n</i> =9)	100.0 (<i>n</i> =7)	94.1 (<i>n</i> =16)
Climbing several flights of stairs			
Yes, limited a lot	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
Yes, limited a little	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
No, not limited at all	80.0 (<i>n</i> =8)	100.0 (<i>n</i> =7)	88.2 (<i>n</i> =15)
Physical health			
Accomplished less than you would like	30.0 (<i>n</i> =3)	14.3 (<i>n</i> =1)	23.5 (<i>n</i> =4)
Limited in the kind of work	20.0 (<i>n</i> =2)	14.3 (<i>n</i> =1)	17.6 (<i>n</i> =3)
Emotional Problems			
Accomplished less than you would like	60.0 (<i>n</i> =6)	28.6 (<i>n</i> =2)	47.1 (<i>n</i> =8)
Did work less carefully	50.0 (<i>n</i> =5)	14.3 (<i>n</i> =1)	35.3 (<i>n</i> =6)
Pain interfere with normal work			
Not at all	70.0 (<i>n</i> =7)	85.7 (<i>n</i> =6)	76.5 (<i>n</i> =13)
Slightly	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
Quite a bit	20.0 (<i>n</i> =2)	14.3 (<i>n</i> =1)	17.6 (<i>n</i> =3)
Felt calm and peaceful			
A little of the time	10.0 (<i>n</i> =1)	28.6 (<i>n</i> =2)	17.6 (<i>n</i> =3)
Some of the time	50.0 (<i>n</i> =5)	14.3 (<i>n</i> =1)	35.3 (<i>n</i> =6)
Most of the time	30.0 (<i>n</i> =3)	57.1 (<i>n</i> =4)	41.2 (<i>n</i> =7)
All of the time	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
Have a lot of energy			
A little of the time	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)
Some of the time	50.0 (<i>n</i> =5)	71.4 (<i>n</i> =5)	58.8 (<i>n</i> =10)
Most of the time	20.0 (<i>n</i> =2)	14.3 (<i>n</i> =1)	17.6 (<i>n</i> =3)
All of the time	20.0 (<i>n</i> =2)	14.3 (<i>n</i> =1)	17.6 (<i>n</i> =3)
Felt downhearted and depressed			
None of the time	30.0 (<i>n</i> =3)	14.3 (<i>n</i> =1)	23.5 (<i>n</i> =4)
A little of the time	0.0 (<i>n</i> =0)	42.9 (<i>n</i> =3)	17.6 (<i>n</i> =3)
Some of the time	50.0 (<i>n</i> =5)	28.6 (<i>n</i> =2)	41.2 (<i>n</i> =7)
Most of the time	10.0 (<i>n</i> =1)	14.3 (<i>n</i> =1)	11.8 (<i>n</i> =2)
All of the time	10.0 (<i>n</i> =1)	0.0 (<i>n</i> =0)	5.9 (<i>n</i> =1)

Physical or mental health interfered with social activities

None of the time	10.0 (n=1)	42.9 (n=3)	23.5 (n=4)
A little of the time	30.0 (n=3)	28.6 (n=2)	29.4 (n=5)
Some of the time	30.0 (n=3)	14.3 (n=1)	23.5 (n=4)
Most of the time	30.0 (n=3)	14.3 (n=1)	23.5 (n=4)

Levels of depression. Table 8 summarizes the mean depression scores and severity of symptoms reported for each group and the total sample as measured by the Quick Inventory of Depressive Symptomatology– Self-Report (QIDS-SR₁₆). In the week prior to baseline, nearly half (47.1%) reported moderate symptoms of depression; over a third (35.3%) reported mild symptoms of depression; and 17.7% reported subclinical symptoms. There were no differences between the two exercise groups in the percentage of elevated depression scores at baseline ($p = 1.00$), or between the mean depression score of the control group ($M = 8.8, SD = 4.4$) versus the BI group at baseline ($M = 10.2, SD = 4.4$), $t(14) = 0.62, p = 0.55$. All participants reported present levels of hedonic capacity to be in a “normal” range and thus were not experiencing anhedonia at baseline.

Table 8

Quick Inventory of Depressive Symptomatology– Self-Report (QIDS-SR₁₆) at baseline

	BI (n = 10) <i>M (SD) or %</i>	C (n = 6) <i>M (SD) or %</i>	Total (n = 16) <i>M (SD) or %</i>
QIDS-SR depression score	10.2 (SD=4.4)	8.8 (SD=4.4)	9.7 (SD=4.3)
Severity of symptoms			
Moderate	60.0% (n=6)	28.6% (n=2)	47.1% (n=8)
Mild	20.0% (n=2)	42.9% (n=3)	35.3% (n=5)

None

20.0% (n=2)

14.3% (n=1)

17.7% (n=3)

Note. One participant from the C group did not complete the measure due to interviewer error.

Psychological/emotional history. Half of study women (50%) had been treated for emotional or psychological problems in an inpatient setting, and 37.5% had received outpatient services. One woman (6.3%) received a pension for a psychiatric disability. While nearly two-thirds of women (62.5%) reported no depression or anxiety in the 30 days prior to treatment enrollment, over two-thirds (68.8%) reported lifetime depression and over one-third (37.5%) reported a past history of serious anxiety. Three study participants (18.8%) reported trouble controlling violent behavior in the 30 days prior to SUD treatment admission, and 43.8% reported one or more such episodes (lifetime). Though no study participants reported suicidal ideation in the 30 days prior to treatment admission, five women (31.3%) reported one or more suicide attempts (lifetime). One-fourth (25%) of women had been prescribed psychotropic medication for psychological/emotional problems in the 30 days prior to treatment admission, and 18.8% of participants had experienced psychological or emotional problems every day in the 30 days prior to treatment entry. Based on these self-report data, the interviewer felt nearly two-thirds (62.3%) of participants would benefit from additional psychological counseling or evaluation.

Employment/financial support history. Nearly one third of women (31.3%) stated they were unemployed for most of the past three years, with one-fourth reporting they worked full time (25%). Employment issues were of concern to most women, with 87.5% rated as in need of additional counseling for employment/financial support issues.

Legal history. For half of the participants (50%), their admission to residential treatment center was prompted or suggested by the criminal justice system, and 68.8% were on parole. Ten participants (62.5%) entered SUD treatment at Rubicon from a controlled environment, and of those, 60% came from jail. Most women (93.8%) had been charged and convicted of criminal offenses in their lifetime, with one-half (50%) detained or incarcerated in the 30 days prior to treatment admission. At treatment admission, 50% of participants were rated in need of further legal counseling.

Family/social history. Study participants were fairly evenly split in how they spent their free time socially, with 31.3% spending it with family, 31.3% spending it alone, and 37.5% spending it with friends. Nearly one half of women (43.7%) reported having no close friends. Most women reported that they did not have conflicts with their family or other friends (62.5% and 81.3%, respectively). The majority of women reported emotional abuse (87.5%), physical abuse (81.3%), and sexual abuse (68.8%) in their lifetime. All participants (100%) endorsed symptoms that were rated as needing additional family and/or social counseling.

Table 9

Psychosocial and Substance Use Measures from the Addiction Severity Index (ASI)

	Range	Total Sample <i>n</i> = 16 <i>M</i> (<i>SD</i>) or %
Entry to SUD treatment from controlled environment		62.5
Of those <i>n</i> = 10:		
Jail		60.0
Alcohol/drug treatment		20.0
Medical treatment		10.0
Psychiatric treatment		10.0
Medical		
Hospitalizations	0-11	2.25 (2.8)

Chronic medical illness		68.6
Prescribed medication		62.5
Medical disability		0.0
No. days medical problem	0-30	7.9 (11.4)
Interviewer rating $\geq 4^*$		56.3
Employment		
Full-time		25.0
Part-time (regular hours)		18.8
Part-time (irregular hours)		12.2
Controlled environment		12.5
Unemployed		31.3
Interviewer rating $\geq 4^*$		87.5
Alcohol		
No. days used in past 30 days	0-26	2.9 (6.9)
No. years used (lifetime)	0-31	8.3 (9.3)
No. days 3+ drinks in past 30 days	0-26	2.5 (6.9)
No. years 3+ drinks (lifetime)	0-31	8.1 (9.4)
Attended alcohol treatment		37.5
No. alcohol treatments	1-8	4.8 (2.9)
Interviewer rating $\geq 4^*$		56.3
Heroin		
No. days used in past 30 days	0-30	10.4 (13.4)
No. years regularly used (lifetime)	0-18	5.5 (6.3)
Other opiates		
No. days used in past 30 days	0-30	2.8 (8.1)
No. years regularly used (lifetime)	0-25	2.6 (6.3)
Sedatives		
No. days used in past 30 days	0-3	0.3 (0.8)
No. years regularly used (lifetime)	0-4	0.4 (1.1)
Cocaine		
No. days used in past 30 days	0-30	9.0 (12.0)
No. years regularly used (lifetime)	0-22	9.5 (6.2)
Marijuana		
No. days used in past 30 days	0-3	0.3 (0.9)
No. years regularly used (lifetime)	0-17	4.0 (5.7)
Polysubstance (2+ drugs [including alcohol]) use		
No. days used in past 30 days	0-30	10.9 (11.8)
No. years regularly used (lifetime)	2-31	12.1 (8.1)
Drug Assessment Summary		
Any previous drug treatment (% yes)		81.3
No. of days with drug problems	0-30	15.5 (13.1)
No. previous drug treatments	1-8	3.5 (2.2)
Interviewer rating $\geq 4^*$		100.0
Legal		
Admission suggested by criminal justice system		50.0
Parole/probation		68.8

Convicted of crimes		93.8
No. of convictions	0-23	7.1 (7.1)
Incarcerated in past 30 days		50.0
Interviewer rating $\geq 4^*$		50.0
Family/Social		
Spends time with friends		31.3
Spends time with friends family		37.5
Spends time alone		31.3
Has close friends		56.3
Has conflict with family		37.5
Has conflict with friends		18.8
Emotional abuse		87.5
Physical abuse		81.3
Sexual abuse		68.8
Interviewer rating $\geq 4^*$		100.0
Psychiatric		
History of inpatient care		50.0
History of outpatient care		37.5
Psychiatric pension		6.3
Depression in past 30 days		37.5
Anxiety in past 30 days		37.5
Depression- lifetime		68.8
Anxiety- lifetime		37.5
Suicide attempt in past 30 days		0.0
Suicide attempt (lifetime)		31.3
Violent behavior in past 30 days		18.8
Violent behavior (lifetime)		43.8
Psychiatric problems in past 30 days		87.5
Psychiatric medication in past 30 days		25.0
Interviewer rating $\geq 4^*$		62.5

Note. One participant from the C group did not complete the ASI. * = in need of additional treatment/services.

Recent (past 90 days) alcohol and other drug use. Because two-thirds of the sample entered treatment from a controlled environment (i.e. jail, alcohol or drug treatment, medical treatment, or psychiatric treatment), substance use patterns were examined separately from those reporting no controlled environment experience during that time. Of participants coming from a controlled environment, three denied use of any illicit substances, seven reported no alcohol use, and eight reported no prescription drug misuse. Participants who reported drug use while in a

controlled environment prior to treatment entry reported that they engaged in such use on average 2.7 days/week ($SD = 1.8$) in the 90 days prior to baseline. Of those participants who reported drug use in that time frame ($n = 7$), over two-thirds (71.4%) reported using cocaine/crack and all but one woman reported heroin use (85.7%). A couple of participants reported using marijuana (28.6%) and one woman reported using speed/ecstasy. Participants ($n = 3$) coming from a controlled environment reported minimal alcohol use ($M = 1.3$ days/week, $SD = 2.1$) in the last 90 days, drinking beer (33.3%), liquor (33.3%), or wine (33.3%). Prescription drugs misused consisted primarily of prescription pain medications, including Methadone, Morphine, Percocet, Oxycodone, and Dilaudid, as well as Xanax, and were misused on average less than one day/week ($M = 0.92$, $SD = 0.54$).

Participants who did not enter treatment from a controlled environment ($n = 6$) reported drug use on average on 3.4 days/week ($SD = 1.8$) in the 90 days prior to baseline. Of those participants who reported drug use in that time frame ($n = 5$), most (80%) reported cocaine/crack use and 80% reported heroin use. Approximately half of participants ($n = 3$) reported alcohol use in the past 90 days, drinking on average 2.5 days/week ($SD = 2.0$). Types of alcohol consumed included beer by all participants (100%), liquor by two of the participants (66.7%), and/or wine by one participant (33.3%). Prescription pain medications were the prescription drugs most commonly misused, including Methadone, Morphine, Oxycodone, and Percocet, and participants ($n = 4$) reported misusing them on average on 1.9 days/week ($SD = 2.5$). One participant denied use of any illicit substances, three reported no alcohol use, and two reported no prescription drug misuse in the 90 days prior to baseline.

Craving for and motivation to change cocaine use. Table 10 shows the mean scores and standard deviations of the Cocaine Craving Scale for each group and the total sample at

baseline. Participants reported relatively low levels of craving for cocaine, and scores ranged from 1.6 to 4, with a mean of 2.3 ($SD = 0.6$). Participants' self-ratings of their motivation to change their cocaine use are shown in Table 11. Overall, women in the study felt they were unlikely to use cocaine again and most felt confident that they could maintain abstinence. While over nearly half of the participants (53%) rated their cocaine use closer to being "A very big problem," a little under a third (29.4%) rated it as "Not a problem at all." The remaining participants (17.7%) were neutral in their rating of their cocaine use as a problem.

Table 10

Cocaine Craving Scale-Brief at baseline

	BI ($n = 10$) $M (SD)$	C ($n = 7$) $M (SD)$	Total ($n = 17$) $M (SD)$
CCQ score	2.1 ($SD=0.3$)	2.5 ($SD=0.9$)	2.3 ($SD=0.6$)

Note. There were no significant differences in craving scores between groups, $t(15) = 1.81$, $p = 0.09$.

Table 11

Participant's Motivation to Change Cocaine Use at Baseline

	BI ($n = 10$) %	C ($n = 7$) %	Total ($n = 17$) %
Use cocaine again in next 3 months			
Very Likely	10.0 ($n=1$)	14.3 ($n=1$)	11.8 ($n=2$)
Neutral	0.0 ($n=0$)	14.3 ($n=1$)	5.9 ($n=1$)
Not likely at all	90.0 ($n=9$)	71.4 ($n=5$)	82.3 ($n=14$)
Could avoid using cocaine completely in next 3 months			
Very Confident	80.0 ($n=8$)	85.7 ($n=6$)	82.3 ($n=14$)

Neutral	0.0 (n=0)	14.3 (n=1)	5.9 (n=1)
Not confident at all	20.0 (n=2)	0.0 (n=0)	11.8 (n=2)
Size of cocaine problem			
Very big problem	40.0 (n=4)	71.4 (n=5)	53.0 (n=9)
Neutral	10.0 (n=1)	28.6 (n=2)	17.7 (n=3)
Not a problem at all	50.0 (n=5)	0.0 (n=0)	29.4 (n=5)
Ready to quit forever			
Very ready	80.0 (n=8)	100.0 (n=7)	88.3 (n=15)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not ready at all	10.0 (n=1)	0.0 (n=0)	5.9 (n=1)
Use cocaine less in next 3 months			
Very likely	30.0 (n=3)	57.1 (n=5)	29.4 (n=5)
Neutral	0.0 (n=0)	14.3 (n=1)	11.8 (n=1)
Not likely at all	60.0 (n=6)	28.6 (n=2)	58.9 (n=10)

Note. One participant from the BI group chose not to provide answers to the last two questions.

Recent (past year) life stressors. Of the $n = 11$ participants who completed the Life Stress Scale at baseline, nearly all (81.8%) reported at least one major stress event in the year prior to treatment entry. Overall, women in the study experienced an average of five ($M = 5.4$) major stressful events in the past year, with the number of events ranging from 1-9 events. Specifically, major stressors in the last year included moving; the death of an important person; loss of income; and/or legal problems. Major stress related to drug or alcohol problems was excluded from these analyses because of its confounding effects on analyses. Six participants did not report on life stressors due to interviewer error.

Attitudes about exercise. Participants were asked to rate their self-efficacy to exercise on the Exercise Confidence Scale (ECS) and how much they identified with benefits and barriers associated with exercise on the Exercise Benefits/Barriers Scale (EBBS). Mean scores and

standard deviations for the ECS are shown in Table 12. Mean scores and standard deviations for the EBBS and each separate subscale (Benefits and Barriers) are shown in Tables 13 through 15.

At baseline, the majority of participants rated themselves as being fairly confident in their ability to exercise in the face of barriers, with means scores of $M = 3.6$ ($SD = 1.1$) on the “Sticking to it” subscale and $M = 3.6$ ($SD = 1.2$) on the “Making time for exercise” subscale of the Exercise Confidence Scale.

Table 12

Exercise Confidence Scale

	Behavioral Incentives <i>n</i> = 9 <i>M</i> (<i>SD</i>)	Control Group <i>n</i> = 7 <i>M</i> (<i>SD</i>)	Total Sample <i>n</i> = 16 <i>M</i> (<i>SD</i>)
“Sticking to it scale”	3.4 (1.5)	3.8 (0.5)	3.6 (1.1)
“Making time to exercise”	3.5 (1.4)	3.6 (1.0)	3.6 (1.2)

Note. Each item was scored between 1-5, with higher numbers indicating greater perception of confidence to exercise. One participant chose not to complete the ECS.

Most participants (81.2%) perceived exercise more favorably than not on the EBBS at baseline. Generally, participants agreed with most of the benefits outlined in the questionnaire, with scores on the Benefits subscale ($M = 81.8$, $SD = 20.1$, range: 29-116) suggesting that participants were moderate in their perception of exercise as positive. Participants most strongly agreed with the items: ‘Exercise improves overall body functioning for me;’ ‘Exercising increases my level of physical fitness;’ ‘I have improved feelings of well being from exercise;’ and ‘Exercising is a good way for me to meet new people.’ In contrast, fewer participants agreed with such items as, ‘Exercising increases my acceptance by others’ and ‘Exercising lets me have

contact with friends and persons I enjoy.’ Overall, participants moderately disagreed with many of the barrier items, suggesting such items on the Barriers scale did not represent barriers participants faced well ($M = 27.9$, $SD = 4.6$, range: 14-56).

Table 13

Exercise Barriers/Benefits Scale

	BI $n = 9$ $M (SD)$	C $n = 7$ $M (SD)$	Total $n = 16$ $M (SD)$
Total Score	124.4 (24.9)	123.3 (19.1)	123.9 (21.1)
Benefits score	109.0 (81.2)	82.6 (18.2)	81.8 (20.1)
Barriers score	26.8 (5.7)	29.3 (2.6)	27.9 (4.6)

Note. One participant did not complete enough questions on the EBBS for scoring.

Table 14

Exercise benefits scale: mean and standard deviation of each questionnaire item.

Perceived Benefit Items	$M (SD)$
Life Enhancement Subscale	
41: Exercise improves overall body functioning for me.	3.2 (1.02)
34: Exercising increases my mental alertness.	3.1 (0.86)
32: Exercising improves my self-concept.	3.0 (0.87)
36: Exercise improves the quality of my work.	3.0 (0.87)
35: Exercise allows me to carry out normal activities without becoming tired.	2.9 (1.09)
25: My disposition is improved by exercise.	2.9 (0.66)
26: Exercising helps me sleep better at night.	2.9 (1.03)
29: Exercise helps me decrease fatigue.	2.9 (0.83)

Physical Performance Subscale

15: Exercising increases my level of physical fitness.	3.2 (0.88)
43: Exercise improves the way my body looks.	3.1 (0.99)
7: Exercise increases my muscle strength.	3.1 (0.86)
22: Exercise increases my stamina.	3.1 (0.75)
31: My physical endurance is improved by exercising.	3.1 (0.97)
17: My muscle tone is improved with exercise.	3.0 (0.94)
23: Exercise improves my flexibility.	2.9 (1.09)
18: Exercising improves functioning of my cardiovascular system.	2.9 (0.90)

Psychological Outlook Subscale

20: I have improved feelings of well being from exercise.	3.2 (0.73)
8: Exercise gives me a sense of personal accomplishment.	3.1 (0.86)
1: I enjoy exercise.	3.0 (0.87)
10: Exercising makes me feel relaxed.	2.9 (0.86)
2: Exercise decreases feelings of stress and tension for me.	2.9 (0.93)
3: Exercise improves my mental health.	2.9 (1.09)

Social Interaction Subscale

30: Exercising is a good way for me to meet new people.	3.2 (0.75)
38: Exercise is good entertainment for me.	2.9 (0.78)
11: Exercising lets me have contact with friends and persons I enjoy.	2.5 (0.87)
39: Exercising increases my acceptance by others.	2.4 (0.96)

Preventive Health Subscale

5: I will prevent heart attacks by exercising.	3.0 (1.00)
27: I will live longer if I exercise.	2.9 (1.03)
13: Exercising will keep me from having high blood pressure.	2.8 (1.02)

All Benefits items of all subscales	3.0 (0.14)
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Note. Each item was scored between 1-5, with higher numbers indicating greater perception of benefit. One participant did not complete enough questions for scoring.

Table 15

Exercise barrier scale: mean and standard deviation of each questionnaire item

Perceived Barrier Items	<i>M (SD)</i>
Exercise Milieu Subscale	
42: There are too few places for me to exercise.	2.2 (0.88)
9: Places for me to exercise are too far away.	2.0 (0.79)
12: I am too embarrassed to exercise.	1.9 (0.93)
14: It costs too much money to exercise.	1.9 (0.90)
16: Exercise facilities do not have convenient schedules for me.	1.9 (0.49)
28: I think people in exercise clothes look funny.	1.7 (0.79)
Time Expenditure Subscale	
4: Exercising takes too much of my time.	2.0 (0.52)
24: Exercise takes too much time from family relationships.	1.7 (0.49)
37: Exercise takes too much time from my family responsibilities.	1.7 (0.59)
Physical Exertion Subscale	
6: Exercise tires me.	2.5 (0.63)
19: I am fatigued by exercise.	2.4 (0.79)
40: Exercise is hard work for me.	2.3 (0.99)
Family Discouragement Subscale	
33: My family members do not encourage me to exercise.	2.4 (1.00)
21: My spouse (or significant other) does not encourage exercising	1.7 (0.90)
All Barrier items of all subscales	2.0 (0.29)

Note. Each item was scored between 1-5, with higher numbers indicating greater perception of barriers. One participant did not complete enough questions for scoring.

Recent (past 4 weeks) physical activity levels. Table 16 summaries the means and standard deviations of the IPAQ-S for each group and the total sample. Participants reported a mean of 4480 MET-minutes/week ($SD = 4353$) and a median of 3864 MET-minutes/week (IRQ

= 882-5337) of physical activity in an average week from the last four weeks on the IPAQ-S at baseline, with no significant differences between groups $t(13) = 1.23, p = 0.24$. On average, this included 617 min/wk of walking (10.3 hrs/week), 307 min/wk of moderate-intensity physical activity (5.1 hrs/week), and 135 min/wk of vigorous-intensity activity (2.3 hrs/week).

Table 15

Recent Metabolic Equivalent Minutes per Week of Exercise (MET-minutes/week) Reported on the IPAQ-S at baseline

	BI <i>n</i> = 9 <i>M</i> (<i>SD</i>)	C <i>n</i> = 6 <i>M</i> (<i>SD</i>)	Total <i>n</i> = 15 <i>M</i> (<i>SD</i>)
Total Score	5589.9 (5119.7)	2816.1 (2361.8)	4480.4 (4353.0)

Note. Two participants did not provide enough information on the IPAQ-S to determine their MET values.

Midpoint Assessments

Three weeks into the six-week intervention period (study midpoint), study participants were weighed and had waist and hip measurements re-measured. Participants also completed the MMS and the IPAQ-S.

Anthropometric measurements. The BMI data for study participants at midpoint are shown in Table 17, with waist-to-hip ratio data shown in Table 18. Six participants did not have a weight recorded. At study mid-point, nearly half (42.9%) of participants had BMIs that were classified as in the obese or morbidly obese range. Overall, participants presented with an average BMI in the obese range ($M = 31.9, SD = 10.0$, range: 23.3-53.6), and average waist-to-hip (WHR) ratio in the moderate overall health risk range ($M = 0.85, SD = 0.7$, range: 0.76-0.98).

Table 16

Body mass index (BMI) at midpoint

BMI Classification	BI (n=5) %	C (n=2) %	Total (n=7) %
Morbidly obese (35 or higher)	20.0 (n=1)	0.0 (n=0)	14.3 (n=1)
Obese (30 - 34.99)	20.0 (n=1)	50.0 (n=1)	28.6 (n=2)
Overweight (25 – 29.99)	40.0 (n=2)	50.0 (n=1)	42.9 (n=3)
Normal (18.5 – 24.99)	20.0 (n=1)	0.0 (n=0)	14.3 (n=1)

Note. Six participants did not have their weight recorded.

Table 17

Waist-to-hip (WHR) ratio at midpoint

Health Risk Based on WHR	Behavioral Incentives (n = 8) %	Control Group (n = 4) %	Total Sample (n = 12) %
High (0.85 or higher)	37.5 (n=3)	50.0 (n=2)	41.5 (n=5)
Moderate (0.81 to 0.85)	25.0 (n=2)	25.0 (n=1)	25.0 (n=3)
Low (0.80 or below)	37.5 (n=3)	25.0 (n=1)	33.2 (n=4)

Note. One participant did not have waist and hip measurements recorded.

Motivation to change cocaine use. Table 19 summarizes participants' self-ratings of their motivation to change their cocaine use at study midpoint. Study participants continued to report that they felt that they were unlikely to use cocaine again and most felt confident that they could maintain abstinence. Nearly one-third of the participants (30.8%) rated their cocaine use closer to being "A very big problem" and over half (53.9%) rated it close to being "Not a problem at all." The remaining participants (15.7%) were neutral in their rating of their cocaine use as a problem.

Table 18

Participant's Motivation to Change Cocaine Use at Midpoint

	Behavioral Incentives (n = 9) %	Control Group (n =4) %	Total Sample (n =13) %
Use cocaine again in next 3 months			
Very Likely	11.1 (n=1)	25.0 (n=1)	15.4 (n=2)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not likely at all	88.9 (n=8)	75.0 (n=3)	84.6 (n=11)
Could avoid using cocaine completely in next 3 months			
Very Confident	66.7 (n=6)	100.0 (n=4)	76.9 (n=10)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not confident at all	33.3 (n=3)	0.0 (n=0)	23.1 (n=3)
Size of cocaine problem			
Very big problem	22.2 (n=2)	50.0 (n=2)	30.9 (n=4)
Neutral	11.1 (n=1)	25.0 (n=1)	15.7 (n=2)
Not a problem at all	66.6 (n=6)	25.0 (n=1)	53.9 (n=7)
Ready to quit forever			
Very ready	88.9 (n=8)	100.0 (n=4)	92.3 (n=12)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)

Not ready at all	11.1 (n=1)	0.0 (n=0)	7.7 (n=1)
Use cocaine less in next 3 months			
Very likely	44.4 (n=4)	50.0 (n=2)	46.2 (n=6)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not likely at all	55.5 (n=5)	50.0 (n=2)	53.9 (n=7)

Physical activity levels. Participants reported a mean of 2485.3 MET-minutes/week (*SD* = 2011.5) and a median of 1822.5 MET-minutes/week (IRQ = 611-4345) of physical activity on the IPAQ-S at midpoint. On average, this included 996.6 min/wk of walking (16.6 hrs/week), 870.8 min/wk of moderate-intensity physical activity (14.5 hrs/week), and 933.3 min/wk of vigorous-intensity activity (15.5 hrs/week). Four participants did not provide enough information on the IPAQ-S to determine their total MET values.

Study Completion

As described in earlier in Figure 1, only nine of the 17 women (52.9% completed the assessments at the end of the six-week intervention period. This included five out of 10 participants from the BI group and four out of seven participants from the C group. The follow-up measures included: ASI (Alcohol/Drug and Psychiatric modules only), QIDS-SR, SHAPS, anthropometric measurements, general health survey, urine drug toxicology, CCQ, MMS, ECS, EBBS, and IPAQ-S.

Drug and alcohol and psychological/emotional problems. At the end of the six-week intervention, study participants did not report drinking in the past 30 days. One participant reported using other opiates on five days out of the last 30 days, and another participant reported smoking cocaine/crack on one day. Half of the participants (50.0%) reported depression and one-third (33.3%) reported anxiety in the 30 days prior to the end of the intervention. Two study participants (33.3%) reported trouble controlling violent behavior during this time frame. There

was no report of recent (past 30 day) suicidal ideation, and half of the women (50%) were prescribed psychotropic medication in the 30 days prior to study completion. One woman experienced psychological or emotional problems every day in the 30 days prior to the end of the intervention, and other women experienced similar problems on average on 5.8 days out of the last 30 days. Three participants had not completed the ASI at time of analysis.

Levels of depression. The means and standard deviations on the QUIDS-SR at baseline and at the six-weeks assessment are shown in Table 20. At the 6-week assessment, two-thirds (66.6%) of participants reported mild symptoms of depression and the remaining one-third (33.3%) reported subclinical symptoms, reflecting an overall significant decrease in reported symptoms of depression ($M = 4.8, SD = 3.2, t(23) = 3.0, p = .007$ (Figure 7). Further, when depression scores from those participants who completed the depression measure at both baseline and study completion were compared across the time points (Figure 8), depression scores at completion had decreased nearly four points ($M = 3.8, t(8) = 2.4, p = .04$). Similar to baseline, all participants reported levels of hedonic capacity to be in the “normal” range and thus were not experiencing anhedonia at the intervention period.

Table 19

Change in Quick Inventory of Depressive Symptomatology– Self-Report (QUIDS-SR₁₆) scores over intervention period

	Baseline Score <i>M (SD)</i>	6-week Assessment Score <i>M (SD)</i>	Change Score	<i>p</i>
Total sample	9.7 (4.3)	4.8 (3.2)	-4.9	.0068*
Behavioral incentives	10.2 (4.4)	4.6 (3.4)	-5.6	.0275*
Control	8.8 (4.4)	5.0(3.5)	-3.8	.1876

Matched total sample	8.6 (3.8)	4.8 (3.2)	-3.8	.0446*
Matched behavioral incentives	10.0 (3.9)	4.6 (3.4)	-5.4	.0647
Matched control	6.7 (3.4)	5.0 (3.5)	-1.7	.4934

Note. * = statistically significant at $p < .05$

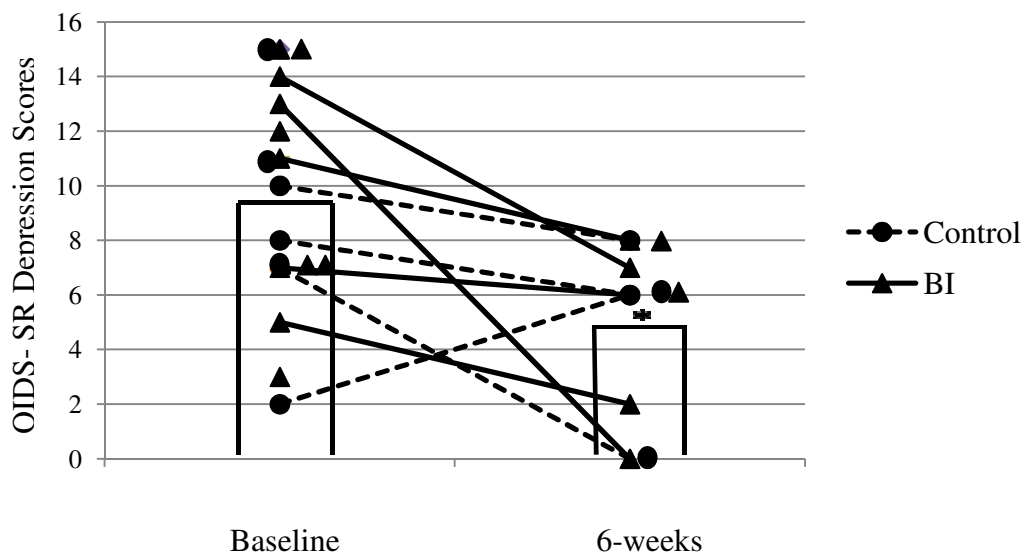


Figure 7. Depression scores of all participants at baseline and at the end of the 6-week intervention.

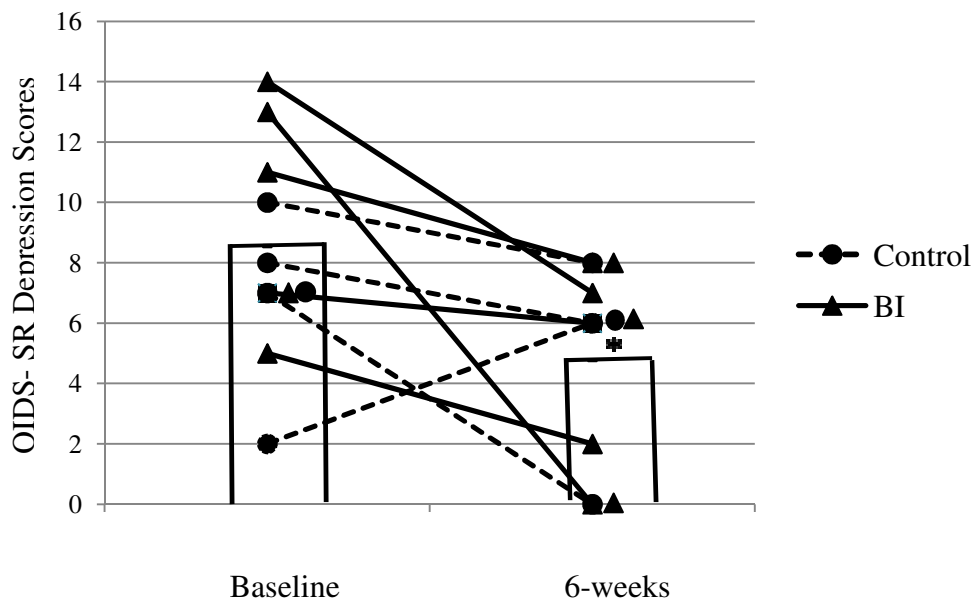


Figure 8. Depression scores of participants remaining in the study at end of the 6-week intervention at baseline and study completion.

Anthropometric measurements. As shown in Table 21, over half (55.6%) of participants presented with a BMI in the obese to morbidly obese range at the end of the intervention period. Overall, participants presented with an average BMI in the obese range ($M = 32.8$, $SD = 9.0$, range: 24.7-53). Table 22 summarizes the WHR of participants, with the average WHR in the moderate overall health risk range ($M = 0.82$, $SD = 0.11$, range: 0.66 – 1.02).

To assess the effect of group assignment (BI or C) on anthropometric measurements, a MLM for repeated measures was run for the outcome variables (BMI and WHR). A ML model was fit to the outcome variables using a diagonal covariance structure. For BMI, the first ML model fit included one between subjects factor (Group: Control, Behavioral Incentives), one within subject factor (Time: 3 assessment time points), and the interaction between Group and Time. In the first model fit, the Group by Time interaction was not significant ($p = .932$) and thus was dropped from the model. The second ML fit included the between subject factor

(Group) and the within subject factor (Time). In this model, the Group effect was not significant ($p = .226$) and the Time effect was not significant ($p = .614$).

Similarly, for WHR, the first ML model fit included one between subjects factor (Group: Control, Behavioral Incentives), one within subject factor (Time: 3 assessment time points), and the interaction between Group and Time. In the first model fit, the Group by Time interaction was not significant ($p = .730$) and thus was dropped from the model. The second ML fit included the between subject factor (Group) and the within subject factor (Time). In this model, the Group effect was not significant ($p = .843$) and the Time effect was not significant ($p = .085$). Taken together, these analyses demonstrate that BMI and WHR did not significantly differ by group, and neither BMI nor WHR changed significantly change over time, regardless of group.

Table 20

BMI at end of intervention period

BMI Classification	BI ($n = 5$) %	C ($n = 4$) %	Total ($n = 9$) %
Morbidly obese (35 or higher)	20.0 ($n=1$)	0.0 ($n=0$)	11.1 ($n=1$)
Obese (30 - 34.99)	40.0 ($n=2$)	50.0 ($n=2$)	44.4 ($n=4$)
Overweight (25 – 29.99)	20.0 ($n=1$)	25.0 ($n=1$)	22.2 ($n=2$)
Normal (18.5 – 24.99)	20.0 ($n=1$)	25.0 ($n=1$)	22.2 ($n=2$)

Table 21

Waist-to-hip (WHR) ratio at end of intervention period

Health Risk Based on WHR	Behavioral Incentives (n = 5) %	Control Group (n = 4) %	Total Sample (n = 9) %
High (0.85 or higher)	40.0 (n=2)	25.0 (n=1)	33.3 (n=3)
Moderate (0.81 to 0.85)	0.0 (n=0)	25.0 (n=1)	11.1 (n=1)
Low (0.80 or below)	60.0 (n=3)	50.0 (n=2)	55.5 (n=5)

General health status. In general, the pattern of responses was similar to that reported at baseline, as shown in Table 23. Specifically, three-fourths (75.0%) of women completing the six-week assessment rated their health as either “Excellent” or “Very good,” and the majority (87.5%) continued to report no difficulty with moderate activities. Further, three-fourths (75.0%) reported they did not accomplish less than they would like. Most (87.5%) did not find that they were limited in the kind of work that they did because of their physical health. One-third of women (37.5%) reported accomplishing less than they would like because of emotional problems, and half (50.0%) reported that they did work less carefully than usual for similar reasons.

Table 22

General health status at baseline and end of six-week intervention

	Baseline Total <i>n</i> = 17 %	End of Intervention Total <i>n</i> = 8 %
General health		
Excellent	17.6 (<i>n</i> =3)	25.0 (<i>n</i> =2)
Very good	23.5 (<i>n</i> =4)	50.0 (<i>n</i> =4)
Good	52.9 (<i>n</i> =9)	12.5 (<i>n</i> =1)
Fair	5.9 (<i>n</i> =1)	12.5 (<i>n</i> =1)
Moderate activities		
Yes, limited a little	5.9 (<i>n</i> =1)	12.5 (<i>n</i> =1)
No, not limited at all	94.1 (<i>n</i> =16)	87.5 (<i>n</i> =7)
Climbing several flights of stairs		
Yes, limited a lot	5.9 (<i>n</i> =1)	0.0 (<i>n</i> =0)
Yes, limited a little	5.9 (<i>n</i> =1)	25.0 (<i>n</i> =2)
No, not limited at all	88.2 (<i>n</i> =15)	75.0 (<i>n</i> =6)
Physical health		
Accomplished less than you would like	23.5 (<i>n</i> =4)	25.0 (<i>n</i> =2)
Limited in the kind of work	17.6 (<i>n</i> =3)	12.5 (<i>n</i> =1)
Emotional Problems		
Accomplished less than you would like	47.1 (<i>n</i> =8)	37.5 (<i>n</i> =3)
Did work less carefully	35.3 (<i>n</i> =6)	50.0 (<i>n</i> =4)
Pain interfere with normal work		
Not at all	76.5 (<i>n</i> =13)	37.5 (<i>n</i> =3)
Slightly	5.9 (<i>n</i> =1)	37.5 (<i>n</i> =3)
Moderately	0.0 (<i>n</i> =0)	25.0 (<i>n</i> =2)
Quite a bit	17.6 (<i>n</i> =3)	0.0 (<i>n</i> =0)
Felt calm and peaceful		
A little of the time	17.6 (<i>n</i> =3)	0.0 (<i>n</i> =0)
Some of the time	35.3 (<i>n</i> =6)	62.5 (<i>n</i> =5)
Most of the time	41.2 (<i>n</i> =7)	37.5 (<i>n</i> =3)
All of the time	5.9 (<i>n</i> =1)	0.0 (<i>n</i> =0)
Have a lot of energy		
A little of the time	5.9 (<i>n</i> =1)	12.5 (<i>n</i> =1)
Some of the time	58.8 (<i>n</i> =10)	75.0 (<i>n</i> =6)
Most of the time	17.6 (<i>n</i> =3)	12.5 (<i>n</i> =1)
All of the time	17.6 (<i>n</i> =3)	0.0 (<i>n</i> =0)
Felt downhearted and depressed		
None of the time	23.5 (<i>n</i> =4)	25.0 (<i>n</i> =2)
A little of the time	17.6 (<i>n</i> =3)	37.5 (<i>n</i> =3)
Some of the time	41.2 (<i>n</i> =7)	37.5 (<i>n</i> =3)
Most of the time	11.8 (<i>n</i> =2)	0.0 (<i>n</i> =0)

All of the time	5.9 (n=1)	0.0 (n=0)
Physical or mental health interfered with social activities		
None of the time	23.5 (n=4)	37.5 (n=3)
A little of the time	29.4 (n=5)	37.5 (n=3)
Some of the time	23.5 (n=4)	25.0 (n=2)
Most of the time	23.5 (n=4)	0.0 (n=0)

Note. One participant did not complete questions from the general health survey.

Urinalysis drug toxicology screen. At the end of the intervention period, participants provided a urine sample that was assayed using an eight-panel drug screen. All participants screened negative for six of the eight drugs in the assay (including cocaine, opiates, amphetamines, methamphetamine, sedative hypnotics, and methadone), and one woman tested positive for both marijuana/THC and benzodiazepines. The participant denied use of either substance but did not submit another sample for retesting.

Craving for and motivation to change cocaine use. Figures 9 and 10 show the Cocaine Craving scores at baseline and six-week assessment (end of intervention) for different subgroups of women. Overall, at the end of the intervention period, participants reported levels of craving for cocaine similar to those found at baseline ($M = 1.9$, $SD = 0.6$) (see Table 24). Similarly, when levels of craving from those participants who completed the cocaine craving measure at both baseline and study completion were compared across the time points, no significant differences were found, $t(16) = 0.45$, $p = 0.66$.

Table 23

Participant's Levels of Craving for Cocaine at the End of the Intervention Period

	Baseline M (SD)	Completion M (SD)	Change Score	p
Total sample (n=18)	2.3 (0.6)	1.9 (0.6)	0.4	>.05
Behavioral incentives (n=11)	2.1 (0.3)	2.0 (0.7)	0.1	>.05
Control (n=7)	2.5 (0.9)	1.7 (0.5)	0.8	>.05
Matched total sample (n=9)	2.0 (0.3)	1.9 (0.6)	0.1	>.05
Matched behavioral incentives (n=5)	2.0 (0.3)	2.0 (0.7)	0.0	>.05
Matched control (n=4)	2.1 (0.3)	1.7 (0.5)	0.4	>.05

Note. Samples sizes denoted (n) are for baseline; sample size at completion for total sample was n = 9 for the total sample, n = 5 for the BI group, and n = 4 for the C group.

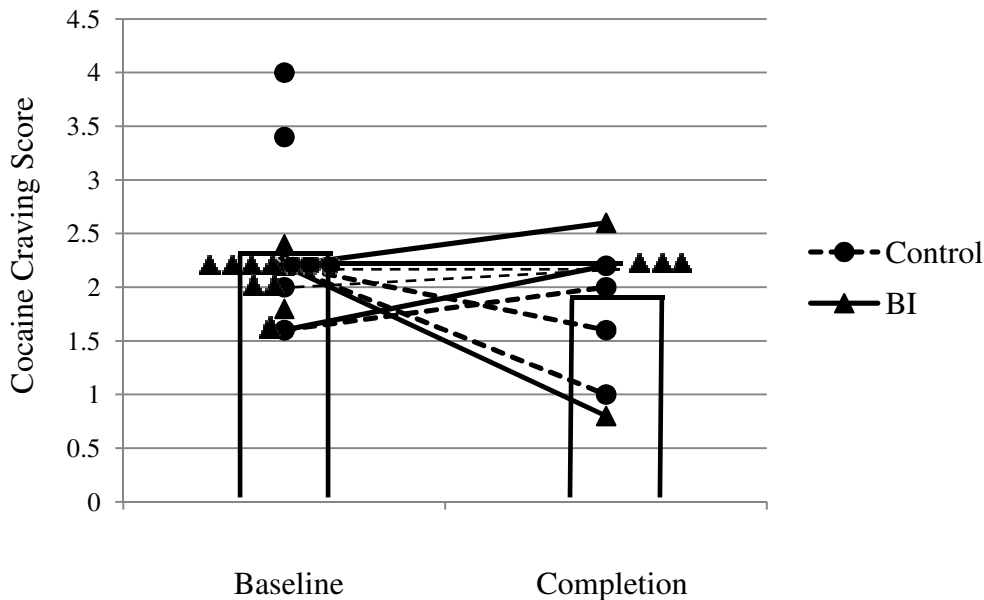


Figure 9. Cocaine craving scores of participants at baseline and at the end of the 6-week intervention.

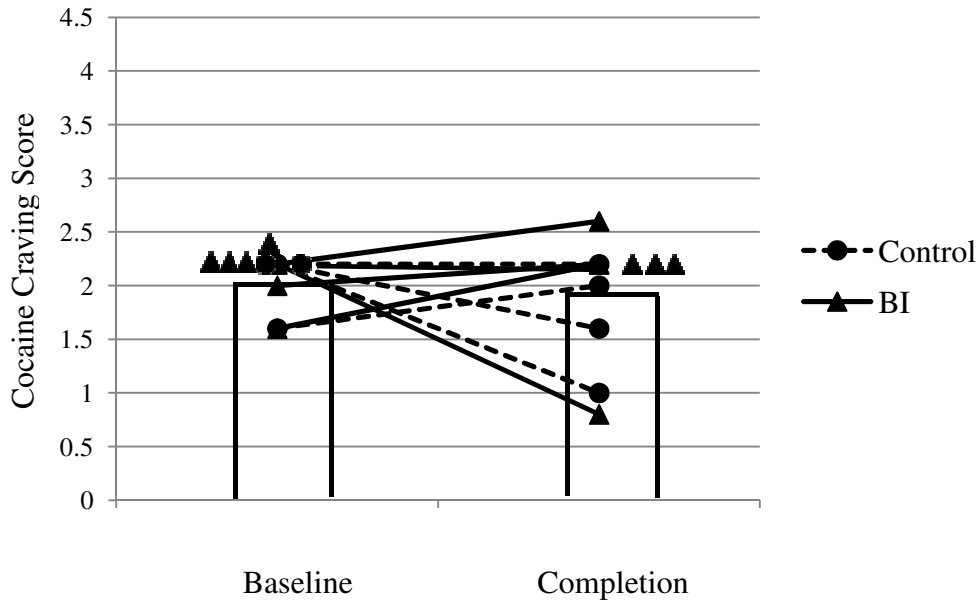


Figure 10. Cocaine craving scores of participants remaining in the study at end of the 6-week intervention at baseline and study completion.

As shown in Table 25, participants generally reported that they were unlikely to use cocaine again and felt confident that they could maintain abstinence. Over half (57.1%) stated it was “Not likely at all” they would use less cocaine in the next three months, 42.9% reported that it was “Very likely.” While over one-half (57.1%) of the women rated their cocaine use as “A very big problem,” others (42.9%) rated it as “Not a problem at all.”

Table 24

Participant's Motivation to Change Cocaine Use at End of Intervention Period

	Behavioral Incentives (n=4) %	Control Group (n=3) %	Total Sample (n=7) %
Use cocaine again in next 3 months			
Very Likely	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not likely at all	80.0 (n=4)	100.0 (n=3)	100.0 (n=7)
Could avoid using cocaine completely in next 3 months			
Very Confident	80.0 (n=3)	100.0 (n=3)	85.7 (n=6)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not confident at all	20.0 (n=1)	0.0 (n=0)	14.3 (n=1)
Size of cocaine problem			
Very big problem	25.0 (n=1)	66.7 (n=2)	42.9 (n=3)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not a problem at all	75.0 (n=3)	33.3 (n=1)	57.1 (n=4)
Ready to quit forever			
Very ready	100.0 (n=4)	100.0 (n=3)	100.0 (n=7)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not ready at all	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Use cocaine less in next 3 months			
Very likely	50.0 (n=2)	33.3 (n=1)	42.9 (n=3)
Neutral	0.0 (n=0)	0.0 (n=0)	0.0 (n=0)
Not likely at all	50.0 (n=2)	66.7 (n=2)	57.1 (n=4)

Note. Two participants (one from each group) chose not to provide answers to the MMS.

Attitudes about exercise. Table 26 summarizes the means and standard deviations on the Exercise Confidence Scale at baseline and at the end of the intervention. At the end of the intervention period, the majority of participants rated themselves as being fairly confident in their ability to exercise in the face of barriers. Mean scores on the “Sticking to it” subscale ($M = 3.3$ ($SD = 0.6$)) and “Making time for exercise” subscale ($M = 3.8$ ($SD = 0.7$)) reflected no significant changes in scores across time, $t(14) = 0.84$, $p = 0.41$ and $t(12) = 0.48$, $p = 0.64$, respectively.

Table 25

Change in Exercise Confidence Scale scores at end of intervention period

	Baseline Score <i>M (SD)</i>	6-week Assessment Score <i>M (SD)</i>	Change Score	<i>p</i>
Sticking to it scale				
Matched total sample	3.7 (1.2)	3.3 (0.6)	-0.4	> .05
Matched BI	3.4 (2.1)	3.4 (0.6)	0.0	> .05
Matched control	3.8 (0.7)	3.2 (0.6)	-0.6	> .05
Making time to exercise				
Matched total sample	3.5 (1.5)	3.8 (0.7)	+0.3	> .05
Matched BI	3.5 (1.7)	4.1 (0.4)	+0.6	> .05
Matched control	3.6 (1.3)	3.4 (0.8)	-0.2	> .05

Note. One participant chose not to complete the ECS at baseline and end of intervention.

As shown in Table 27, there was no significant change in mean scores on the EBBS among participants who completed the measure at both baseline and end of the intervention period ($M = 123.2, SD = 27.3$ versus $M = 119.8, SD = 28.7, t(14) = , p = 0.69$). Overall, three-fourths of study participants (75.0%) perceived exercise more favorably than not at the end of the intervention. Generally, participants continued to moderately agree with items about the benefits of exercise ($M = 82.8, SD = 28.46$, range: 35-116), suggesting that participants were moderate in their perception of exercise as beneficial at the end of the six-week intervention. Overall, participants moderately disagreed with many of the barrier items, again reflecting that items on the Barriers scale did not represent barriers participants faced well ($M = 33.1, SD = 6.92$, range: 25-43).

Table 26

Change in Exercise Barriers/Benefits Scale total scores at end of intervention period

	Baseline Score <i>M (SD)</i>	6-week Assessment Score <i>M (SD)</i>	Change Score	<i>p</i>
Total sample	123.9 (21.1)	119.8 (28.7)	-4.1	> .05
BI	123.3 (19.1)	122.5 (28.1)	-0.8	> .05
Control	124.4 (24.9)	117.0 (33.4)	-7.4	> .05
Matched total sample	123.2 (27.3)	119.8 (28.7)	-3.4	> .05
Matched BI	122.4 (31.5)	122.5 (28.1)	+0.1	> .05
Matched control	124.3 (25.6)	117.0 (33.4)	-7.3	> .05

Note. One participant chose not to complete the EBBS at the six-week assessment.

Physical activity levels of residential women with SUD. Participants reported a mean of 3768.2 MET-minutes/week (SD = 5470.4) and a median of 1620 MET-minutes/week (IRQ = 607.5-4638) of physical activity on the IPAQ-S at the end of the 6-week intervention. On average, this included 388 min/wk of walking (6.5 hrs/week), 184 min/wk of moderate-intensity physical activity (3.1 hrs/wk), and 244 min/wk of vigorous-intensity activity (4.1 hrs/wk). Two participants did not provide enough information on the IPAQ-S to determine their MET values at the end of the 6-week intervention.

To assess the effect of group assignment (BI or C) on physical activity levels, a MLM for repeated measures was run for the outcome variable (total MET-minutes/week). A ML model was fit to the outcome variables using a diagonal covariance structure. A ML model fit included one between subjects factor (Group: Control, Behavioral Incentives), one within subject factor (Time: 3 assessment time points), and the interaction between Group and Time. In the first model fit, the Group by Time interaction was not significant ($p = .407$) and thus was dropped from the model. The second ML fit included the between subject factor (Group) and the within subject factor (Time). In this model, the Group effect was not significant ($p = .958$) and the Time effect was not significant ($p = .376$). This analysis suggests that there was not a significant difference between the groups with regards to physical activity, or a significant difference in physical activity levels over time.

Prizes for Behavioral Incentives Group

Table 28 summarizes the means and numbers of prizes across the categories of “good job” (verbal), small, large, and jumbo, as well as prizes earned by BI participants. Participants in the BI group had the opportunity to draw prizes for exercising for 30-minutes during scheduled exercise sessions, in addition to earning bonus draws for engaging in moderate intensity exercise

during these sessions. On average, participants earned the chance to draw for prizes on seven of the 18 eligible days over the six-week intervention period ($M = 7.0$, $SD = 4.37$). The prizes drawn were distributed among the various values, with participants earning on average 12.7 “Good Job” tokens, 8.9 “Small” prizes, and 2.8 “Large” prizes; no participant drew a “Jumbo” prize token during the study. In total, each participant earned approximately 24 prizes in total ($M = 24.4$, $SD = 17.31$), and 12 prizes of monetary value ($M = 11.7$, $SD = 8.33$), with average earnings of \$86.50 per participant in the BI group.

Table 27

Prizes distributed per participant over course of six-week intervention

	Range	M (SD)
No. of days prizes drawn	0-14	7.0 (4.37)
Highest number of draws for a single exercise session	0-9	4.9 (2.85)
No. of bonus draws	0-12	4.4 (4.27)
No. of “Good Job”	0-25	12.7 (9.14)
No. of Small prizes	0-19	8.9 (6.35)
No. of Large prizes	0-7	2.8 (2.53)
No. of Jumbo prizes	0	0.0 (0.00)
Total number of prizes	0-51	24.4 (17.31)
Total number of monetary prizes	0-26	11.7 (8.33)

Discussion

Taken together, current study findings provided benchmark data on the utility of BI for promoting physical activity in a sample of women with cocaine dependence in residential SUD treatment. The primary outcome variables (percentage of sessions completed and total time spent in scheduled sessions) were used for effect size estimations, which were then used to perform power analyses so that sample size calculations could be estimated for the design of a Stage II RCT. The sample size estimated was similar to other RCTs that used Petry's "fishbowl" method (Petry et al., 2005) or other BI procedures to promote change in a variety of smoking and drug use behaviors, including abstinence from substance use (Higgins et al., 2010; Hser et al., 2011; Raiff, Jarvis, Turturici, & Dallery, 2013; Washio et al., 2011). Notably, effect sizes were calculated to be moderate, suggesting that BI is best viewed as one tool among several that can and should be used to incentivize exercise behavior. Further, a significant Group effect demonstrated that the two groups (BI and C) differed in the total minutes spent in the scheduled exercise sessions, with the BI group significantly greater than the C group. These promising findings support the use of BI procedures to promote exercise compliance.

The purpose of the present study was to test a novel approach for promoting compliance with physical activity as one component of residential SUD treatment, and to provide benchmark data about the use of BI to promote exercise in women with cocaine dependence. Poor compliance with exercise protocols has been a critical barrier to empirical studies of physical activity and its effects on treatment and recovery for persons with SUDs. Prior to starting the current study, the author of this dissertation used the Rounsaville et al. (2001) guidelines for therapies development to complete Stage Ia therapy development activities. The preliminary work was funded by a small Community Based Participatory Research (CBPR) grant from the

VCU Institute for Women's Health. These initial Stage Ia activities focused on intervention development and manual writing, needs assessment surveys, and instrument development, as well as focus groups with the target population to obtain feedback about acceptability and feasibility of the proposed new intervention. Working in concert with researchers, the approach engaged community drug abuse treatment staff providers, as well as program, in the design of the intervention and selection of the target behavior (30 minutes treadmill walking) at two levels (any intensity exercise and moderate level exercise). The group also discussed schedule and magnitude of reinforcement, and other core intervention components.

The present study built upon the original CBPR grant and proceeded to Stage Ib, in which a pilot RCT with $N = 26$ was completed comparing women randomized to a BI and C group. Overall, a Stage Ib pilot trial typically aims to demonstrate: a) participant acceptance of a new treatment; b) the ability to recruit a sufficient number of participants from the target population; c) feasibility of treatment delivery with the proposed types of research staff/clinicians, participants, and treatment setting; d) clinically significant participant improvement over the course of treatment in at least one important outcome area; and e) the likely effect size to be obtained contrasting the new treatment group with a comparison group to be used to determine the sample size for a Stage II RCT (Rounsaville et al., 2001). Stage I, comprised of Stage Ia and Ib, uses basic behavioral research strategies to develop new psychosocial treatments, with the goal of better understanding the behavioral change process and promoting positive change. Thus, the present Stage Ib study was among the first to examine whether BI, an evidence-based practice for reducing drug use and promoting treatment attendance, could be modified and applied to promote regular exercise during a six-week period of residential SUD treatment for women with cocaine dependence.

In a small controlled trial, the study first examined whether BI would promote greater compliance with an exercise regimen than standard care. Next, controlled trial findings informed effect size. It also allowed the dissertation author to pilot test a diverse array of measures, and in doing so, also better characterize the target population. This was important to future research, as little was known to-date about the physical activity and exercise habits of these women. Finally, study findings will inform and promote further research in a promising area that has received too little attention, in part because low compliance rates have limited research focused on exercise as an adjunct to treatment for people with SUDs.

Effect size estimation

Though the originally proposed study expected $N = 50$ participants, the present study enrolled $N = 26$ due to many factors described in later sections. Notably, Stage Ib studies are not powered to detect significant intervention and control group differences, and power was not expected to be adequate for this pilot clinical trial, even if the target original sample size had been achieved. The goal of this Stage Ib research was to obtain effect size estimates for a future RCT of BI compared to standard care. For effect size estimation, two outcome measures were used (i.e., percentage of 30 minute scheduled treadmill sessions completed over a six week period; total time treadmill walking during scheduled sessions over a six week period). Present study findings supported a small to medium effect size, and based off of this, between 70-90 participants per group would be needed to detect intervention and control group differences. These sample size estimates are similar to other RCTs that used the Petry method, used as a template for the present study, to promote long durations of abstinence among cocaine- or heroin-dependent women (Olmstead & Petry, 2009; Petry et al., 2005). Studies that used other BI procedures (e.g. a continuous reinforcement schedule) to promote change in smoking (e.g.

Higgins et al., 2010; Raiff, Jarvis, Turturici, & Dallery, 2013) and other drug use behavior (e.g. Hser et al., 2011) also had similar sample sizes.

As a Stage Ib therapy development pilot study, this study data is useful in effect size estimation in preparation for a Stage II RCT. However, the expected sample size of $N = 50$ was not achieved. For Stage Ib pilot studies, the broad guideline that 15-30 subjects per cell be included is given, and little difference between the methodology of the pilot and larger study trials expected (other than the scale of work and amount of preparation needed) (Rounsaville et al., 2001). The present study not only had a smaller $N = 26$, but faced a number of methodological issues as well, that requires these estimates to be interpreted cautiously.

Effect of BI on exercise behaviors

While we did not expect to see statistically significant differences, nonetheless, we proceeded to test the four hypotheses comparing the BI group to the C group. First, we predicted that participants in the BI treatment group would complete more scheduled treadmill sessions than the C group over the six week intervention period. While the absolute values were in the predicted direction (48.0% versus 33.6%, respectively), this difference was not statistically significant.

Previous studies have demonstrated modest effects when contingency management was used in physical activity interventions. In a study of obese adults, modest material rewards had positive effects on attendance to supervised walking sessions (Jeffery, Wing, Thorson, & Burton, 2012). In another study, dually-diagnosed adults from a day-treatment program participated in a 12-week program three days/week, and received tokens for active participation in 45-minute exercise sessions, which could be traded in for food or clothing items (Merriman, Barnett, & Jarry, 1996). These participants were found to demonstrate improved muscle endurance,

cardiorespiratory endurance, and flexibility (Merriman et al., 1996). Finally, in a small study of children, television viewing was made contingent on pedaling a stationary bicycle for experimental participants, but not for control participants (Faith et al., 2001). Over the 12 weeks intervention period, participants in the experimental group significantly increased their pedaling (Faith et al., 2001).

The second hypothesis stated that participants in the BI treatment group would spend significantly more total time (minutes) walking on the treadmill in scheduled sessions than those in the C group over the intervention period. Again, the difference between the absolute values was in the direction that supported the hypothesis (208.0 minutes versus 152.2 minutes, respectively), but was not significant. However, a ML model demonstrated that the two groups (BI and C) differed in the total minutes spent in the scheduled exercise sessions. Specifically, the estimated marginal mean for the BI group was significantly greater than that of the control group (13.3 minutes versus 9.2 minutes, respectively). This suggests that BI procedures would be effective in promoting compliance with treadmill walking among a group of women with SUDs, though these findings should be interpreted cautiously, as they are largely model dependent. Further, because additional exercise completed by study participants outside of scheduled sessions was not recorded, the clinical relevance of these findings is difficult to determine.

The third hypothesis stated that participants in the BI treatment group would complete significantly more consecutive exercise sessions (i.e. demonstrate sustained exercise) compared to the C group over the six week intervention period. In the field of SUD treatments, long-term continuous abstinence is recognized by most as the most desirable outcome (Trivedi et al., 2011). The primary goal of SUD treatment is to avoid relapse to drug use, thereby maintaining sustained

drug abstinence. Similarly, exercise guidelines established by leading groups such as the ACSM and Department of Health and Human Services recommend daily, sustained exercise (Haskell et al., 2007; USDHHS, 2008).

Continuous reinforcement procedures (i.e., rewarding every instance of the target behavior monetarily) are effective, and make the schedule and implementation of CM procedures easier in some regards (Higgins et al., 1994). With such BI procedures, a missed target (e.g. positive drug screen) results in a substantially decreased reinforcer value, returning to baseline reinforcement level (Higgins et al., 1994). Such procedures likely protect against relapse because of the greater monetary loss that accompanies an instance of drug use following a period of abstinence, ultimately promoting sustained abstinence rather than discrete instances of non-drug use (Roll et al., 2006). However, continuous reinforcement procedures can be quite costly if a participant meets the goal of successfully sustaining behavior change. Because sustained behavior change is clinically the most meaningful, however, cost-effective methods have great utility. Therefore, effective behavioral incentives interventions that use increasing magnitudes of reinforcement, but in the form of “draws,” with a reset contingency to promote sustained periods of abstinence address both goals of treatment (Petry, 2011).

Similarly, the present study used BI procedures with escalating vouchers for consecutively attended exercise sessions and a reset contingency for a missed exercise session. Based on the ACSM’s recommendations that most adults should engage in moderate-intensity cardiorespiratory exercise for at least 30 minutes/day on at least 5 days/week, consistent exercise on multiple days of the week is considered essential to improving and maintaining physical fitness and overall health for most adults (Garber et al., 2011). Further, Williams and colleagues (2011) found that effects of exercise on affect and withdrawal symptoms appear to be short-lived

and suggested that sustained adherence to exercise programs is imperative to impact smoking cessation outcomes. However, given the sedentary habits of the target population (Islam, Dillon, Acevedo, Nora, & Svikis, 2012), the target of exercising three days/week was selected to approach recommendations for the benefits of regular exercise, without overwhelming study participants with an overly intensive program.

Because continuous behaviors are considered the ideal outcome in SUD treatment programs (Trivedi et al., 2011), sustained exercise is likely an important target behavior for physical activity interventions with SUD populations. In the present study, the number of consecutively completed scheduled sessions ranged from 0 to 9 for the BI group and 0 to 6 for the C group. The difference in the number of consecutive exercise sessions completed by the BI group and C group was not significant, though the mean scores were in the BI supportive direction, as expected (4.2 versus 2.9, respectively).

Closer examination of individual exercise sessions revealed that in some instances, participants presented to a scheduled session prepared to exercise, but were not permitted to exercise by research staff for safety reasons (e.g. elevated blood pressure level), or were physically unable to complete a full 30 minutes of exercise (e.g. significant pain). In these cases, participants were considered to have demonstrated some level of compliance with the target behavior, and the variable of consecutive exercise sessions *attended* was created. Though the difference in the number of consecutive exercise session attended was not statistically significant, interestingly, the BI group demonstrated approximately twice the increase in mean number of sessions attended (4.9 versus 2.9).

Finally, participants who were unable to attend a scheduled exercise session were asked to notify research staff, and in a number of these cases, absences were considered excused if

verified with an external source. In these cases, though participants did not present to exercise, they demonstrated conscientiousness toward the target behavior by notifying research staff of their schedule conflict prior to their scheduled session. To account for this level of compliance with the target behavior, the variable consecutive exercise sessions *accounted for* was created. Again, the BI group had a higher mean number of sessions accounted for than the C group, though the difference between groups was not statistically different (7.9 versus 5.4, respectively).

Consistent with research on the importance of the schedule of BI (Roll & Higgins, 2000; Roll & Shoptaw, 2006), reset contingencies were utilized to promote sustained behavior. However, an excused absence did not result in reset to baseline reinforcement levels for those in the BI group. Still, a BI participant was unable to earn token draws for the missed session unless rescheduled in advance, resulting in an overall decrease in the number of potential draws earned by that participant. Essentially, participants forfeited additional prizes by virtue of not being able to follow the prescribed escalation to its highest magnitudes. Instead, the participant had to repeat the lower magnitude portion of the progression, thereby potentially losing even more opportunities to draw prize tokens. In a number of cases, participants were able to reschedule an exercise session with research staff, keeping their overall number of opportunities to draw prizes the same. However, in other situations, sessions were missed for unexpected reasons (e.g. inclement weather, miscommunication regarding holiday schedules, RA illness) and additional sessions were not added on to the intervention period. This decision was likely a function of keeping a cohort of women on the same schedule, an unclear protocol in this regard, limited RA schedules, and frankly, oversight on the part of research staff.

The choice to not add additional sessions to the intervention period could have been viewed as punishment by some participants. In fact, the potential negative side effects related to

resets has been studied at length given that the reset contingency is a form of punishment (Sarafino, 2001), and punishment procedures can result in negative side effects (Sidman, 1989). Kazdin (1972) initially determined that a reset contingency was a safer alternative to more aversive forms of punishment, and extensive literature since then has not demonstrated negative effects for reset contingencies (Versek et al., 2010). However, reset contingencies have been found to be associated with negative emotional reactions such as mild anxiety and verbal or physical aggression on occasion (Schloss, 1983). In future studies, the flexibility to add additional sessions may be beneficial, though careful consideration to the parameters around the lengthening of the intervention period should be considered. Also, shaping procedures may be appropriate to provide reinforcement for approximations of the target behavior (e.g. attending a session with the intention of exercising) (Lattal, 2010), which may be beneficial for participants who are unable to complete an exercise session for legitimate, verified reasons.

The fourth hypothesis stated that participants in the BI treatment group would complete significantly more moderate intensity sessions compared to the C group over the six week intervention period. Interestingly, all participants who completed a 30-minute exercise session did so at a moderate intensity, regardless of group. Therefore, the finding that there was no significant difference between the number of exercise sessions completed by group does not support this hypothesis, though absolute values trend in the supportive direction (48% versus 33.6%). This finding supports the selection of moderate intensity exercise as a target behavior over light-intensity (Daniel et al., 2004) or vigorous-intensity exercise (Blair, LaMonte, & Nichman, 2004; Perri et al., 2002). This suggests that participants who chose to exercise were at a fitness level that allowed them to sustain moderate intensity exercise for 30 minutes.

In summary, the hypotheses of the study were not supported. However, selection of the study sample size was consistent with Stage Ib guidelines, and did not assure adequate power to detect statistical significance. Rather, the primary goal of this Stage Ib research was to obtain effect size estimates for the BI intervention and explore other specific aims.

Specific aims of study

As a Stage Ib pilot study, the primary goal of the present study was to examine the following outcome measures: a) the total number of 30 minute treadmill sessions; and b) the total amount of time (minutes) spent treadmill walking, and use this data to inform effect size estimation in preparation of a subsequent Stage II large-scale RCT. Consistent with Rounsaville et al. (2001) guidelines, other specific aims focused on: a) Evaluation of participant acceptance of BI procedures; b) Confirmation of reasonableness of recruitment procedures (e.g., ability to enroll participants at the projected rate); c) Examination of feasibility of BI implementation and the ability to track the number of exercise sessions and time spent in treadmill walking for the BI and C groups; and d) Monitoring of participant response to the BI and C conditions and the extent to which BI motivates women to engage in physical activity through treadmill walking.

Acceptance of BI procedures

As a staged treatment development project, the present study examined how acceptable BI procedures were to study participants. Most participants appeared to understand and accept the randomization process to either the “Exercise” or “Exercise Plus” group, and this in part was likely facilitated by their involvement in opening the envelope holding their randomization code, and being able to determine to which group they were assigned using posted signs in the research office. Only one participant, who was in the control “Exercise” group, required repeated explanations of why she was not earning prizes several exercise sessions into the study.

BI procedures were used to target compliance with treadmill walking, and promote moderate-intensity walking. Interestingly, previous research demonstrated that individuals identify a variety of factors that prevent them from exercising, including a lack of one or more of the following: motivation, time, access to facilities or equipment, energy, workout partner, and self-efficacy (Chinn, White, Harland, Drinkwater, & Raybould, 1999; King, Castro, Wilcox, Eyler, & Sallis, 2000; Ryan et al., 1997; Trost et al., 2002), but less often physical ability. In the present study, when study participants were asked if they were limited in completing moderate activities because of their physical health, the vast majority of participants responded “No, not at all,” suggesting that women did not abstain from participation in the exercise program because they believed that they were physically incapable. However, the amount of sustained exercise recommended by leading groups like the ACSM and DHHS may be overwhelming for women who are not only physically unfit, but also short on time (Linke, Gallo, & Norman, 2011). Even within the context of residential treatment and access to on-site treadmills, participants presented with numerous time conflicts, including appointments for doctor’s appointments or job interviews, being placed on sanction by Rubicon staff and/or nurse, or assignment of mandatory facility programs or duties (e.g. kitchen service). Though not statistically significant, more women in the BI group demonstrated conscientiousness toward the target behavior by notifying research staff of their schedule conflict prior to their scheduled session. Therefore, BI procedures may have been an acceptable way to increase conscientiousness towards the target behavior of exercise by serving as a source of extrinsic motivation.

Reasonableness of recruitment procedures

Stage Ib trials are also employed to confirm reasonableness of recruitment procedures, including the ability to enroll participants at the projected rate. Based on previous research,

Rubicon was expected to admit approximately 16 women/month into residential treatment, and approximately 80% of these women (N=12/month) were expected to be approved for 60 days of residential care (Meshberg-Cohen, Nilson, Suwal, Lee, & Svikis, 2009; Choi, Langhorst, Meshberg-Cohen, & Svikis, 2011). Of the women who were expected to be approved for 60 days of residential treatment, a nominal number (3.4%) were unexpectedly discharged early (Meshberg-Cohen, 2009). During the active phase of the present study, however, Rubicon admitted only 13 women/month into residential treatment. Further, over one-fourth (26.9%) were unexpectedly discharged early due to insurance or other funding issues. This significant reduction in SA treatment stays longer than 30 days was likely related to changes in the funding climate at Rubicon during the present study, which also was evidenced by high staff turnover and difficulty with reimbursement. Similar trends of difficulty retaining highly skilled personnel to deliver effective SUD treatment and recovery services are seen in programs across the country, with the turnover rate for addictions personnel significantly higher than the national average (Knudsen et al., 2003). Further, this pattern is in line with national concerns regarding the “fragile and unstable” infrastructure of many treatment programs, making the implementation of evidence-based care difficult (McLellan & Meyers, 2004). Though Rubicon staff and administration were supportive of the present study’s research efforts, programmatic issues significantly impacted Stage Ib research activities and resulted in lower rates of recruitment and retention than expected.

Yet another factor leading to lower rates of recruitment was a shift in primary drug of choice among women admitted to the program and in the Richmond area more generally. Based on previous research, DSM-IV defined cocaine dependence was overwhelmingly the primary current SUD diagnosis (81.9%) among residential women at Rubicon (Meshberg-Cohen, 2009).

Given these findings, similar rates were expected for present Stage Ib study. However, through a recent Stage Ia survey administered to $N = 97$ Rubicon residents, the self-identified primary drug of choice was heroin (39.2%) followed closely by cocaine/crack (36.1%) (Islam et al., 2012). High rates of opioid abuse/dependence in the past year were found in the present study as well, and equaled that of current cocaine abuse/dependence. Because a DSM-IV-TR diagnosis of Cocaine Abuse/Dependence was specifically required for study enrollment, the change in drug use profiles for Richmond resulted in a slower rate than originally projected. Anecdotally, this shift in the predominant drug of use was noted by Rubicon treatment staff, though treatment cocaine dependence remained a high area of interest. Taken together, these factors resulted in lower rates of recruitment than expected.

Feasibility of BI procedures and implementation

Research implementation issues

To properly execute BI procedures, study staff were required to organize and keep track of the session schedule, the number of draws due at each visit, reset contingencies, and bonus draws. In another study using contingency management procedures, staff were noted to experience difficulty understanding the incentives at times, though these issues were limited and were able to be addressed (Tuten, Svikis, Keyser-Marcus, O'Grady, & Jones, 2012). In the present study, while effort was made to keep the protocol design simple, throughout the study questions about the prize draws due arose, and post-hoc review of the distribution of prized revealed some confusion about the prize distribution. As an additional specific aim of the study, the ability to track the number of exercise sessions and time (minutes) spent treadmill walking for the BI and C groups was examined. BI procedures require observation of the target behavior, personalized attention to all participants, and the opportunity to earn highly desirable prizes and

the withdrawal of this opportunity in instances of non-adherence (Weinstock, Wadson, & VanHeest, 2012). Because RA time was limited, exercise sessions were scheduled with RAs. Specifically, for the pilot study, exercise sessions were required to be scheduled three times/week for six weeks with a RA on a fairly consistent basis throughout the six-week intervention, to allow for direct monitoring of a participant's time and effort spent in an exercise sessions, though participants could exercise ad lib at other times. This resulted in participants ultimately having to not only meet the physical activity aspect of the target behavior, but also required participants to demonstrate the ability to attend scheduled appointments with research staff in a timely manner.

Research design issues

Though scheduled exercise sessions were consistent with the implementation of effective BI procedures, this raised practical issues specific to the present study's research design. First, due to budgetary constraints as a R36-funded dissertation project and unavoidable delays in startup, the dissertation author was not able to be on site during the majority of active recruitment. RA time was not budgeted to have RAs on site to monitor any additional exercise sessions or offer as many additional times for rescheduled sessions as originally anticipated. Further, the original protocol planned to have Rubicon staff trained to monitor exercise sessions as well, though due to high rates of staff turnover this was not feasible. Finally, there was a significant change in staffing after the primary RA hired left the position, necessitating the hiring and training of a new RA mid-study.

Further, a number of scheduling barriers presented throughout the course of the study, and underscored the need for clear communication. For example, questions regarding monitoring arose when the RA for the study was ill and unable to observe a scheduled exercise

session. Similar concerns were present when the university was closed following inclement weather or national holidays. Finally, scheduled exercise sessions required a certain amount of communication between study participants and RAs. To minimize miscommunication, the present study placed a white board the study office and encouraged participants to leave a message for RAs regarding scheduled sessions. Additionally, the RAs often checked with the staff on duty (SOD) office regarding a participant's scheduled or health status. Overall, these experiences affirm the importance of having a committed yet flexible research staff to offer more comprehensive involvement in BI and other study procedures.

Monitoring of participant response to the study conditions

Participants in the BI group earned prizes for meeting the target behavior of treadmill walking, and a bonus draw if moderate intensity exercise was maintained for duration of the exercise session. An additional specific aim of the study was to evaluate the ability to monitor participant response to the BI and C conditions and the extent to which BI motivated women to engage in physical activity through treadmill walking. The present study followed methodology provided in previous studies to create the “gym bag” containing labeled ping pong balls, or tokens (Petry, 2000). Specifically, 500 ping pong balls were used, and each one represented a reward ranging from a reinforcing message (“Good job”; 50% of tokens) to small prizes (snack; 41.8% of tokens) to large prizes (CD player; 8.0%) to a jumbo prize (stereo; 0.2% of tokens). In the present study, participants earned on average 12.7 “Good Job” verbal reinforcers (range: 0-25), 8.9 “Small” prizes (range: 0-19), and 2.8 “Large” prizes (range: 0-7). Interestingly, no participant drew a “Jumbo” prize token, limiting the overall potential motivating power of the lottery-based system. To address the issue of low rates of reinforcement early in studies when the number of draws is low, Petry et al. (2005) found that awarding a single large prize when a

participant first achieved two consecutive weeks of abstinence was beneficial. A similar “booster” prize would have likely strengthened the reinforcement system of the present study.

Additionally, a critical aspect of BI implementation is that tangible reinforcers are provided whenever the target behavior is demonstrated, with immediacy (and magnitude) of the rewards a significant moderator of CM effect sizes (Lussier et al., 2006). For most of the study period, treadmills were located in one room of the residential treatment facility, and prizes were housed in the on-site research office. Immediately following an exercise session in which a participant from the BI group met a target behavior, the participant was asked to accompany the RA to the office to draw tokens for her prizes. However, in some cases, generally due to scheduling, participants were unable to choose their prizes directly following an exercise session. This delay could have negatively affected their reinforcing aspect. For example, one participant who exercised regularly on her own and as part of the study protocol often chose to go on to another activity following an exercise session rather than come to the research office for her prizes. This, in part, suggests that the prizes may have had limited value to her in influencing her exercise behaviors. On the other hand, the participant often chose items that she could share or gift to other residents at the facility, offering a way for her to share her positive reinforcement in a meaningful social context, and perhaps receive additional positive verbal reinforcement. Finally, though the attractiveness of items in the prize cabinet was regularly verbally assessed by RAs throughout the duration of the study (i.e. asking BI participants if there were any items they particularly desired and then purchasing those to stock in the prize cabinet), a more formal and anonymous system of assessing the desirability of items in the prize cabinet may be more fruitful.

Overall, BI procedures appear to have promising effects on motivating women to engage in physical activity through treadmill walking. Careful attention should continue to be paid to the rate at which prizes are distributed and the multiple group effects that the prize system may generate in motivating women to earn more chances for prizes and ultimately, exercise.

Characterization of the target population

Consistent with previous research (Meshberg-Cohen, 2009), study participants were in their late 30's, single, and identified as African-American. Though DSM-IV-TR cocaine abuse/dependence diagnoses were selected for as part of inclusion criteria for the study, rates of opioid abuse/dependence were also high. Health-wise, at baseline many study participants reported one or more chronic medical illnesses, with medication(s) prescribed to treat their chronic medical problems. These medical issues were also reflected in over half of the participants self-rating of their health as only "good." However, most participants reported that they faced no limitation in completing moderate activities or climbing several flights of stairs, and largely did not find that pain interfered with their normal work. Nearly half of participants reported moderate symptoms of depression at the start of the intervention period, and a similar number stated that they had accomplished less than they would have liked as a result of emotional problems and/or felt downhearted and depressed some of the time, consistent with previous findings of low mood in this population (Meshberg-Cohen, 2009). Interestingly, prior to admission to SUD treatment at Rubicon, over half of study participants were in a controlled environment, including jail and other SUD treatment programs. Though it is unknown how prior environment may affect a participant in multiple areas, this may be an important factor to monitor in future studies.

At end of the six-week intervention, over half of participants rated their health as either “excellent” or “very good,” in contrast a similar number rating their health as only “good” at baseline. Women continued to report no difficulty with moderate activities or with climbing several flights of stairs. Participants’ report of their levels of craving for cocaine did not significantly change over the course of the intervention period, though this likely is related to overall low levels of craving reported to start. Levels of craving for cocaine at baseline may have been low in part because many women were coming from a controlled, drug-free environment. Notably, at the end of the six-week intervention, the BI group had significant reductions in depressive symptoms. Given the small sample size remaining at study completion, this reduction in depressive symptoms was likely associated with participants having spent six weeks largely drug free in a supportive residential SUD treatment setting. However, given the inverse relationship between regular exercise and depressive symptoms (Petry, 2011; Weinstock, Barry, & Petry, 2008), reinforcing regular treadmill walking may have had some positive effects with respect to participants’ mental and physical health.

Regarding study measures, a discrepancy in reporting was noted on the MMS, regardless of assessment time. Responses to the question “On a 1 to 10 scale, how likely are you to use cocaine less than you used to, in the next 3 months?” were often inconsistent with responses to other items on the same measure. For example, at baseline over half of women reported that they were *not* at all likely to “use cocaine *less*” in the next three months, though most reported that they were very confident that they could avoid using cocaine completely in the next three months and very ready to quit using cocaine forever. Though the reasons are unclear, this may be related to misinterpretation the referenced question, and more specifically missing the word “less” in the question.

Finally, study participants' responses to common barriers to exercise suggested that the sample did not strongly identify with common barriers named on this measure. Similar findings were reported by Lovell and colleagues (2010) in another study with women. These barriers may have still been limiting, as other research has demonstrated that even if the perceived benefits of exercise outweigh the perceived barriers, the accrued benefits must be viewed as *much* greater than their difficulties (El Ansari & Phillips, 2004). Similarly, research suggests that perceived barriers could be more influential over behaviors than perceived benefits (Nahas & Goldfine, 2003; Ransdell et al., 2004). Additionally, Stage Ia survey results demonstrated that the target population may have faced practical barriers not included on standardized measures, thus not adequately capturing the barriers truly faced (Islam et al., 2012). Survey findings demonstrated that over one-third (35.8%) of women interviewed did not have shoes suitable for exercising (walking) and 27.6% did not have appropriate attire for such activities. These findings were supported by study participants who presented to exercise sessions in sandals or without wearing a bra because of limited resources.

Study Implications and Future Directions

The present study has a number of important implications, and serves to inform multiple choice points in the development of additional Stage I activities and ensuing Stage II development projects. Some key factors to consider are reviewed here.

As previously discussed, the reinforcement schedule used in BI procedures can have a significant impact on the targeted behavior. The present study revealed the practical issue of a participant presenting to exercise, thus demonstrating compliance, only to be turned away by research staff because of protocol-defined safety concerns. To address the issue of reinforcing not only “completers,” but “attenders” as well, BI to reward behaviors leading to the targeted

behavior (i.e. 30 minutes of exercise) would likely be beneficial. Similar shaping procedures have been used to provide reinforcement in other studies, where approximations of the targeted behavior (e.g. reduced drug use versus abstinence) have been beneficial for participants who are unable to achieve the singly defined target (Lattal, 2010). For example, one participant presented to her first two sessions, but was not allowed to exercise because of her elevated heart rate. The participant presented to her third session, though interestingly, at that time reported that she did not feel like exercising, and went on to miss the rest of her sessions during the intervention period. Such behavior suggests that the participant may have been disappointed by not being able to complete the target behavior, and shaping procedures may have served well to encourage her to continue to attempt to engage in physical activity.

Similarly, reinforcing less intensive forms of physical activity may ultimately help support sustained exercise recommended for health benefits. Reinforcing multiple bouts of shorter duration, or intermittent, aerobic exercise (typically two to three bouts of 10–15 min each per day) may promote greater compliance with an exercise regimen, though evidence to support this is lacking at this time (Linke et al., 2011). However, Stage Ia activities found that though the target population was very interested in potential exercise programs, few had experience with treadmill walking (Islam et al., 2012). Specifically, nearly 70 % had either never used a treadmill before or had limited experience with treadmill use (26.5% and 42.9% respectively). This inexperience was also observed in the present study, during which one participant unexpectedly jumped off the treadmill when she finished because she subsequently noted she did not know how to stop it, or a number of others who only felt comfortable if they were holding on to the treadmill bars while walking. These findings suggest that additional orientation to basic treadmill use may would be important in future studies.

Research is increasingly focusing on practical ways to improve continuing care and recovery in SUD treatment. While evidence on the effectiveness of individual “coaching” in the recovery process is limited, McKay et al. (2009) suggest that “coaches” can be helpful in monitoring client progress and addressing their co-occurring problems as needed. For the present study, it was clear that RAs in part served as “coaches” to study participants. Anecdotal reports suggest the nature and extent of coaching varied based on the relationship between RAs and various participants, and this may have influenced participant motivation and interest in the study. For example, one participant presented to a session during the fifth week of the intervention, and reported that she was not going to exercise because she was upset regarding an argument that had taken place with another resident. After talking for a short period of time with the RA, the participant decided to complete her exercise session and later reported that she felt better. Another participant enjoyed listening to music while treadmill walking. She and one RA quickly discovered shared music interests that could be played via the RA’s smartphone. With other participants, RAs reported frustration due to missed appointments and rescheduled sessions. More systematic monitoring of such interpersonal factors would be important as they could affect participant motivation and interest in exercise and the overall study.

The protocol used to make sure it was safe for a participant to exercise is also important to consider for this population of women, especially in balancing the overall well-being of study participants with having a protocol that is not overly stringent. As a pilot study, it was important to comply with established safety parameters, and have RAs with expertise to ensure safety but not overly restrict the opportunity to exercise. In post-hoc review of the data, RAs may have in fact been overly conservative at times. While the RAs not experienced in exercise physiology were appropriately cautious in making safety decisions, these decisions could have seemed

punitive to some participants who reported a desire to exercise but were not allowed to. As a Stage Ib trial, this was unavoidable but should be carefully evaluated and monitored in future studies. Though having staff to supervise the exercise sessions has been widely supported as beneficial to increasing attendance rates (Dolezal et al., 2013; Ussher et al., 2008), the selection of that staff member is key. Dolezal and colleagues (2013) suggested that involvement of a qualified exercise specialist in residential treatment facilities can augment physical fitness, and other studies have hired exercise physiologists to supervise sessions (Brown et al., 2010). The study findings and past research underscore the importance of having a multidisciplinary-trained RA to execute BI procedure and monitor exercise safety.

Technology has offered promise for increasing treatment access, effectiveness, and availability, particularly for underserved populations (Carroll & Rounsaville, 2010; Bickel, Christensen, & Marsch, 2011). Others have suggested using technological advancements in measurement (e.g., electronic diaries, smartphone applications, interactive voice response systems) (Trivedi et al., 2011), all of which can be tailored to focus on exercise. Devices worn to monitor activity (e.g. pedometers, FitBit) are increasingly used in studies of physical activity, and permit simultaneous measurement of multiple behaviors, including physical activity, without direct, in-person oversight. One potential barrier to greater rates of exercise compliance was the way in which the target behavior of exercise was monitored. Because participants were asked to individually schedule regular exercise sessions, and required to present during their “time slot,” participants essentially were asked to comply with multiple behaviors, including appointment attendance and timeliness. Further, participants may have preferred other types of or settings for exercise (Brown et al., 2010). In a Stage Ia survey, the vast majority of women (84.7%) reported that they would be interested in participating in an exercise class (e.g. yoga, Pilates, Tai Chi),

and 51% reported that they preferred to exercise in a public setting (e.g. a gym) (Islam et al., 2012). However, walking has been supported as a preferred exercise choice among patients in SUD treatment (Abrantes et al., 2011), and past research found that over half (53.1%) of the target population reported being “very interested” in treadmill walking, with another one-fourth (25.5%) “somewhat interested” (Islam et al., 2012).

Gender, racial, and socioeconomic differences are important factors to consider when designing future interventions and selecting assessment measures. To date, though limited, most studies of exercise in SUD treatment settings enrolled predominantly men (Brown et al., 2010; Dolezal et al., 2013), many of whom were Caucasian, well-educated, and employed (Brown et al., 2010). A number of demographic factors also have been shown to be related to smoking cessation success in CM programs, including gender (male) and race (Caucasian) when examined with univariate analyses, though not maintained when examined in multivariate regression models that included marital status, nicotine replacement therapy use, and other factors (Renaud & Halpern, 2010). In a study of three randomized clinical trials of CM examining the interactive effects of sexual abuse history and treatment condition (standard care + CM versus standard care alone) on cocaine abuse or dependence treatment outcomes (retention in treatment, proportion of negative urine samples, and longest duration of abstinence), gender differences were also observed (Petry, Ford, & Barry, 2011). Specifically, women submitted a significantly lower proportion of negative urine samples than men, though rates of negative urines were high overall while in treatment. However, sexual abuse status was significantly related to the proportion of negative urine samples submitted, even after controlling for treatment condition. Interestingly, CM was especially beneficial in increasing LDA in participants with sexual abuse histories than those without (Petry, Ford, & Barry, 2011). Therefore, the gender of

participants in the present study, along with their prevalent abuse histories and other demographic factors, suggest participant complexities that may have significant effects on the success or failure of a CM program that are not yet fully understood.

Additionally, the selection of appropriate self-report measures continues to be a primary area of improvement in the development of future studies as well. For example, scores on the IPAQ-S varied widely, yielding rates of physical activity that were likely significantly elevated. Previous research (Wolin, Heil, Askew, Matthews, & Bennet, 2008) demonstrated only fair correlations between the IPAQ-S and accelerometer-determined physical activity in a sample of African-Americans residing in low-income housing, and low agreement between the two forms of measurement when examining the proportion of individuals classified as meeting CDC/ACSM physical activity recommendations. In that study, low correlations between IPAQ-S and accelerometer-measured physical activity were more prominent among African-American females. This pattern has been observed in studies of physical activity, with questionnaires comparing diverse groups of men and women in general (Resnicow et al., 2003; Matthews et al., 2000). Taken together, this suggests that self-report measurement of physical activity in women remains a challenge, particularly when classifying physical activity levels.

The present study attempted to supplement physical activity data from the scheduled treadmill sessions using exercise logs distributed at the beginning of the six-week intervention. These exercise logs proved ineffective due to very low compliance rates. Only two participants completed the logs and it was clear that RAs needed to encourage and better monitor adherence. This is confirmed by the fact that such logs have been successfully used in previous research with patients in SUD treatment (Brown et al., 2011). Other studies used weekly 7-day recalls to

track unscheduled exercise, suggesting a potentially more successful way to capture physical activity of research participants (Dolezal et al., 2013).

Finally, the literature supports the use of feedback questionnaires and exit surveys to inform future research (Trivedi et al., 2011). Specifically, such innovative assessment tools allow for participant-reported evaluation of the meaningfulness of their response to the study intervention (Trivedi et al., 2011). Brown and colleagues (2011) developed an anonymous feedback questionnaire that allowed SUD patients to record their perceptions of staff knowledge, helpfulness, and availability, as well as the extent to which exercise will help them maintain drug abstinence and attain study goals. Barriers to participating in an exercise study could also be evaluated at multiple time points throughout the study. The questionnaire also included open-ended questions that allowed the discussion of the strengths and weakness of the intervention. Though less formalized, Stage Ia (Islam et al., 2012) and Ib development activities employed interviewer-administered assessments, allowing for some similar information to be collected. As in the Brown et al. (2011) study with anonymous surveys, study participants expressed a desire for nutritional information, as well as overall inclusion of toning or strength training as a component to the program. However, implementing a more regular and anonymous way to collect feedback would undoubtedly better inform the design of future exercise focused research in SUD settings.

Final Thoughts

This dissertation provided benchmark data on the utility of BI for promoting physical activity for women with cocaine dependence. These promising findings support the use of BI procedures to promote exercise compliance. Effect sizes were calculated to be moderate, thus suggesting that BI is best viewed as one tool among several than can and should be used to

incentivize exercise behavior. The facilitation of increased initiation of and adherence to an exercise program will ultimately allow scientists to better evaluate potential benefits of physical activity on treatment outcomes in women with SUDs.

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Appendix A

General Information

- 1) How old are you? _____ yrs.
- 2) Of what race do you consider yourself?
_____ Black/African American _____ Native Hawaiian or Other Pacific Islander
_____ White/Caucasian _____ Asian
_____ American Indian or Alaskan Native _____ Other (Specify: _____)
- 3) How far did you get in school? _____ years (or last grade completed)
(Comments _____)
- 4) What is your marital status?
_____ Single/Never Married _____ Widowed
_____ Married/Living as Married (5+ yrs together) _____ Other _____
_____ Divorced/Separated
- 5) What was your usual employment pattern (year before entering Rubicon)?
_____ Employed Full Time (35+ hrs/week) _____ Homemaker/Mom
_____ Employed Part Time _____ Unemployed/Not Working
_____ Student _____ Disabled
- 6) How many children do you have? _____ kids
How many currently live with you? _____ kids
- 7) Describe your current living situation (past year)
_____ With partner/spouse alone _____ Alone
_____ With partner/spouse and kids _____ With family/friends
_____ With kids alone (single parent) _____ Other

Locator Form

Please provide the names, addresses, and phone numbers of three (3) people who are likely to know where you will be following treatment. This information will be used **only** to contact you to schedule the post-discharge follow-up visit. You will only say that you are participating in a research study. No information about your drug abuse treatment will be disclosed without written informed consent from you.

1) Name: _____

Address: _____

Phone Number: _____

2) Name: _____

Address: _____

Phone Number: _____

3) Name: _____

Address: _____

Phone Number: _____

EXERCISE BENEFITS/BARRIERS SCALE

DIRECTIONS: Below are statements that relate to ideas about exercise. Please indicate the degree to which you agree or disagree with the statements by checking the appropriate boxes below.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I enjoy exercise.				
2. Exercise decreases feelings of stress and tension for me.				
3. Exercise improves my mental health.				
4. Exercising takes too much of my time.				
5. I will prevent heart attacks by exercising.				
6. Exercise tires me.				
7. Exercise increases my muscle strength.				
8. Exercise gives me a sense of personal accomplishment.				
9. Places for me to exercise are too far away.				
10. Exercising makes me feel relaxed.				
11. Exercising lets me have contact with friends and persons I enjoy.				
12. I am too embarrassed to exercise.				
13. Exercising will keep me from having high blood pressure. SA				
14. It costs too much to exercise.				
15. Exercising increases my level of physical fitness.				
16. Exercise facilities do not have convenient schedules for me.				
17. My muscle tone is improved with exercise.				
18. Exercising improves functioning of my cardiovascular system.				
19. I am fatigued by exercise.				
20. I have improved feelings of well being from exercise.				
21. My spouse (or significant other) does not encourage exercising.				
22. Exercise increases my stamina.				
23. Exercise improves my flexibility.				
24. Exercise takes too much time from family relationships.				
25. My disposition is improved with exercise.				
26. Exercising helps me sleep better at night.				

	Strongly Agree	Agree	Disagree	Strongly Disagree
27. I will live longer if I exercise.				
28. I think people in exercise clothes look funny.				
29. Exercise helps me decrease fatigue.				
30. Exercising is a good way for me to meet new people.				
31. My physical endurance is improved by exercising.				
32. Exercising improves my self-concept.				
33. My family members do not encourage me to exercise.				
34. Exercising increases my mental alertness.				
35. Exercise allows me to carry out normal activities without becoming tired.				
36. Exercise improves the quality of my work.				
37. Exercise takes too much time from my family responsibilities.				
38. Exercise is good entertainment for me.				
39. Exercising increases my acceptance by others.				
40. Exercise is hard work for me.				
41. Exercise improves overall body functioning for me.				
42. There are too few places for me to exercise.				
43. Exercise improves the way my body looks.				

EXERCISE CONFIDENCE SURVEY

Below is a list of things people might do while trying to increase or continue regular exercise. We are interested in exercises like running, swimming, brisk walking, bicycle riding, or aerobics classes.

Whether you exercise or not, please rate how confident you are that you could really motivate yourself to do things like these consistently, *for at least six months*.

Please circle one number for each question.
How sure are you that you can do these things?

		I know I cannot	1	2	Maybe I can	3	4	5	I know I can	Does not apply	(8)
21.	Get up early, even on weekends, to exercise.	1	2	3	4	5					(8)
22.	Stick to your exercise program after a long, tiring day at work.	1	2	3	4	5					(8)
23.	Exercise even though you are feeling depressed.	1	2	3	4	5					(8)
24.	Set aside time for a physical activity program; that is, walking, jogging, swimming, biking, or other continuous activities for at least 30 minutes, 3 times per week.	1	2	3	4	5					(8)
25.	Continue to exercise with others even though they seem too fast or too slow for you.	1	2	3	4	5					(8)
26.	Stick to your exercise program when undergoing a stressful life change (e.g., divorce, death in the family, moving).	1	2	3	4	5					(8)
27.	Attend a party only after exercising.	1	2	3	4	5					(8)
28.	Stick to your exercise program when your family is demanding more time from you.	1	2	3	4	5					(8)
29.	Stick to your exercise program when you have household chores to attend to.	1	2	3	4	5					(8)
30.	Stick to your exercise program even when you have excessive demands at work.	1	2	3	4	5					(8)
31.	Stick to your exercise program when social obligations are very time consuming.	1	2	3	4	5					(8)
32.	Read or study less in order to exercise more.	1	2	3	4	5					(8)

MMS

INSTRUCTIONS: Please circle one number for each of the lines below to answer each question in terms of how you're feeling right now, at this moment. If you've answered these questions recently, please don't on purpose try to give the same answer *or* a different answer. Just put how you feel right now, at this moment, whether it's the same or different.

1. On a 1 to 10 scale, how likely are you to use cocaine again, even a little, in the next 3 months?

1-----2-----3-----4-----5-----6-----7-----8-----9-----10
Not at all likely Very likely

2. On a 1 to 10 scale, how confident are you that you could avoid using cocaine completely for the next 3 months, if you decided to try?

1-----2-----3-----4-----5-----6-----7-----8-----9-----10
Not confident at all Very confident

3. On a 1 to 10 scale, how much of a problem do you think your cocaine use is?

1-----2-----3-----4-----5-----6-----7-----8-----9-----10
Not a problem at all A very big problem

4. On a 1 to 10 scale, how ready are you to quit using cocaine completely and forever?

1-----2-----3-----4-----5-----6-----7-----8-----9-----10
Not ready at all Completely ready

5. On a 1 to 10 scale, how likely are you to use cocaine less than you used to, in the next 3 months?

1-----2-----3-----4-----5-----6-----7-----8-----9-----10
Not at all likely Very likely

Cocaine Craving Questionnaire- Brief

Indicate how much you agree or disagree with each of the following statements by placing a single check mark along each line between STRONGLY DISAGREE and STRONGLY AGREE. The closer you place your check mark to one end to the other indicated the strength of your disagreement or agreement. Please complete every item. We are interested in how you are thinking or feeling right now as you are filling out the questionnaire:

1. I want cocaine so bad I can almost taste it.
STRONGLY AGREE _____ STRONGLY DISAGREE
2. I have an urge for cocaine.
STRONGLY AGREE _____ STRONGLY DISAGREE
3. I am going to use cocaine as soon as possible.
STRONGLY AGREE _____ STRONGLY DISAGREE
4. I think that I could resist using “coke” now.
STRONGLY AGREE _____ STRONGLY DISAGREE
5. I crave “coke” right now.
STRONGLY AGREE _____ STRONGLY DISAGREE
6. All I want to use now is cocaine.
STRONGLY AGREE _____ STRONGLY DISAGREE
7. I have no desire for cocaine right now.
STRONGLY AGREE _____ STRONGLY DISAGREE
8. Using cocaine now would make things seem just perfect.
STRONGLY AGREE _____ STRONGLY DISAGREE
9. I will use cocaine as soon as I get the chance.
STRONGLY AGREE _____ STRONGLY DISAGREE
10. Nothing would be better than using “coke” right now.
STRONGLY AGREE _____ STRONGLY DISAGREE

Life Stressors Scale

We'd like to get a sense of the kind of stress that *you* may have experienced *during the past year*. For the next list of items, I'd like you to tell me whether or not they happened in the last year, and *if* they happened, whether they caused minor stress or major stress. [NOTE: if the item has happened, but they say that it caused no stress, just select 'minor stress']

	[1]	[2]	[3]
In the past year . . .	No	Caused Minor Stress	Caused Major Stress
1. Have you moved?	1	2	3
2. Have you had medical problems with (<i>child</i>)?	1	2	3
3. Have you had medical problems with close family members?	1	2	3
4. Have you experienced the death of an important person?	1	2	3
5. Have you had a divorce, break-up, or separation from your partner?	1	2	3
6. Have you had a remarriage or reconciliation with your spouse or partner?	1	2	3
7. Have you had a parent-child separation including long hours at work?	1	2	3
8. Have you had a loss of income?	1	2	3
9. Have you had legal problems?	1	2	3
10. Have you had drug or alcohol problems or addiction?	1	2	3
11. Have you had stress or conflicts in the extended family?	1	2	3
12. Have you had pregnancies, miscarriages, or births?	1	2	3
13. Have you had job-related stress?	1	2	3

In the past year . . .	No	Caused Minor Stress	Caused Major Stress
14. Have you had a loss of job?	1	2	3
15. Have you experienced crime or violent victimization?	1	2	3
16. Have you had unexpected expenses?	1	2	3
17. Has someone in your family had problems with police or court?	1	2	3
18. Have you had problems with where you live (for example, vandalism or not being able to get repairs done by your landlord)?	1	2	3
19. Have you had problems with your neighbors (for example, dogs barking or lots of noise at night)?	1	2	3
20. Have you had problems with people you owe money (for example, calls or letters from collection agencies, landlord threatening to evict you, people harassing you)?	1	2	3

SHAPS

Indicate whether to what extent you agree or disagree with the following statements.

	Strongly Disagree	Disagree	Agree	Definitely Agree
1. I would enjoy my favorite television or radio program				
2. I would enjoy being with family or close friends				
3. I would find pleasure in my hobbies and pastimes				
4. I would be able to enjoy my favorite meal				
5. I would enjoy a warm bath or refreshing shower				
6. I would find pleasure in the scent of flowers or the smell of a fresh sea breeze or freshly baked bread				
7. I would enjoy seeing other people's smiling faces				
8. I would enjoy looking smart when I have made an effort with my appearance				
9. I would enjoy reading a book, magazine or newspaper				
10. I would enjoy a cup of tea or coffee or my favorite drink				
11. I would find pleasure in small things; e.g. bright sunny day, a telephone call from a friend				
12. I would be able to enjoy a beautiful landscape or view				
13. I would get pleasure from helping others				
14. I would feel pleasure when I receive praise from other people				

TIMELINE FOLLOWBACK CALENDAR 2012

Participant ID: _____ Date: ___/___/___ RA: _____
 Visit Type: Baseline Study Follow-up

Alcohol Use

Type of Alcohol Consumed in past **90** days (Check all that apply): Beer Liquor Wine

Complete the Following: Start Date (Day 1): ___/___/___ End Date (yesterday): ___/___/___

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
	1 ^{New Year's}	2	3	4	5	6	7
J	8	9	10	11	12	13	14
	15	16 ^{M. L. King}	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
F	5	6	7	8	9	10	11
	12	13	14 ^{Valentine's Day}	15	16	17	18
	19	20 ^{Presidents' Day}	21	22	23	24	25
	26	27	28	29	1 ^{Ash Wednesday}	2	3
M	4	5	6	7	8	9	10
	11	12	13	14	15	16	17 ^{St. Patrick's Day}
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31
A	1	2	3	4	5	6 ^{Good Friday}	7 ^{Passover}
	8 ^{Easter}	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	1	2	3	4	5
M	6	7	8	9	10	11	12
	13 ^{Mother's Day}	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28 ^{Memorial Day}	29	30	31		

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
						1	2
J	3	4	5	6	7	8	9
U	10	11	12	13	14	15	16
N	17 Father's Day	18	19	20	21	22	23
	24	25	26	27	28	29	30
J	1	2	3	4 Independence Day	5	6	7
U	8	9	10	11	12	13	14
L	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
A	5	6	7	8	9	10	11
U	12	13	14	15	16	17	18
G	19	20	21	22	23	24	25
	26	27	28	29	30	31	1
S	2	3 Labor Day	4	5	6	7	8
E	9	10	11	12	13	14	15
P	16	17 Rosh Hashanah	18	19	20	21	22
	23	24	25	26	27	28	29
O	30	1	2	3	4	5	6
C	7	8 Columbus Day	9	10	11	12	13
T	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31 Halloween	1	2	3
N	4	5	6 Election Day	7	8	9	10
O	11 Veterans' Day	12	13	14	15	16	17
V	18	19	20	21	22 Thanksgiving	23	24
	25	26	27	28	29	30	1
D	2	3	4	5	6	7	8
E	9 Hanukkah	10	11	12	13	14	15
C	16	17	18	19	20	21	22
	23	24 Christmas Eve	25 Christmas	26	27	28	29
	30	31 New Year's Eve					

TIMELINE FOLLOWBACK CALENDAR 2012

Participant ID: _____ Date: ____/____/____ RA: _____

Visit Type: Baseline Study Follow-up

Illicit Drug Use

Type of Illicit Drug(s) Used in past **90** days (Check all that apply):

Marijuana Cocaine/Crack Heroin Hallucinogens Speed/Ecstasy Inhalants

Complete the Following: Start Date (Day 1): ____/____/____ End Date (yesterday): ____/____/____

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
	1 ¹ New Year's	2	3	4	5	6	7
J A N	8	9	10	11	12	13	14
	15	16 ^{M. L. King}	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
F E B	5	6	7	8	9	10	11
	12	13	14 ^{Valentine's Day}	15	16	17	18
	19	20 ^{Presidents' Day}	21	22	23	24	25
	26	27	28	29	1 ^{Ash Wednesday}	2	3
M A R	4	5	6	7	8	9	10
	11	12	13	14	15	16	17 ^{St. Patrick's Day}
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31
A P R	1	2	3	4	5	6 ^{Good Friday}	7 ^{Passover}
	8 ^{Easter}	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	1	2	3	4	5
M A Y	6	7	8	9	10	11	12
	13 ^{Mother's Day}	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28 ^{Memorial Day}	29	30	31		

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
						1	2
J	3	4	5	6	7	8	9
U	10	11	12	13	14	15	16
N	17 Father's Day	18	19	20	21	22	23
	24	25	26	27	28	29	30
J	1	2	3	4 Independence Day	5	6	7
U	8	9	10	11	12	13	14
L	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
A	5	6	7	8	9	10	11
U	12	13	14	15	16	17	18
G	19	20	21	22	23	24	25
	26	27	28	29	30	31	1
S	2	3 Labor Day	4	5	6	7	8
E	9	10	11	12	13	14	15
P	16	17 Rosh Hashanah	18	19	20	21	22
	23	24	25	26	27	28	29
O	30	1	2	3	4	5	6
C	7	8 Columbus Day	9	10	11	12	13
T	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31 Halloween	1	2	3
N	4	5	6 Election Day	7	8	9	10
O	11 Veterans' Day	12	13	14	15	16	17
V	18	19	20	21	22 Thanksgiving	23	24
	25	26	27	28	29	30	1
D	2	3	4	5	6	7	8
E	9 Hanukkah	10	11	12	13	14	15
C	16	17	18	19	20	21	22
	23	24 Christmas Eve	25 Christmas	26	27	28	29
	30	31 New Year's Eve					

TIMELINE FOLLOWBACK CALENDAR 2012

Participant ID: _____ Date: ___/___/___ RA: _____

Visit Type: Baseline Study Follow-up

Prescription Drug Misuse

Name of Prescribed Drug(s) Misused in past **90** days:

1. _____ More than prescribed More often than prescribed Someone else's
2. _____ More than prescribed More often than prescribed Someone else's
3. _____ More than prescribed More often than prescribed Someone else's

Complete the Following: Start Date (Day 1): ___/___/___ End Date (yesterday): ___/___/___

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
	1 ^{New Year's}	2	3	4	5	6	7
JAN	8	9	10	11	12	13	14
	15	16 ^{M. L. King}	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
FEB	5	6	7	8	9	10	11
	12	13	14 ^{Valentine's Day}	15	16	17	18
	19	20 ^{Presidents' Day}	21	22	23	24	25
	26	27	28	29	1 ^{Ash Wednesday}	2	3
MAR	4	5	6	7	8	9	10
	11	12	13	14	15	16	17 ^{St. Patrick's Day}
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31
APR	1	2	3	4	5	6 ^{Good Friday}	7 ^{Passover}
	8 ^{Easter}	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	1	2	3	4	5
MAY	6	7	8	9	10	11	12
	13 ^{Mother's Day}	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28 ^{Memorial Day}	29	30	31		

2012	SUN	MON	TUES	WED	THURS	FRI	SAT
						1	2
J	3	4	5	6	7	8	9
U	10	11	12	13	14	15	16
N	17 Father's Day	18	19	20	21	22	23
	24	25	26	27	28	29	30
J	1	2	3	4 Independence Day	5	6	7
U	8	9	10	11	12	13	14
L	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
A	5	6	7	8	9	10	11
U	12	13	14	15	16	17	18
G	19	20	21	22	23	24	25
	26	27	28	29	30	31	1
S	2	3 Labor Day	4	5	6	7	8
E	9	10	11	12	13	14	15
P	16	17 Rosh Hashanah	18	19	20	21	22
	23	24	25	26	27	28	29
O	30	1	2	3	4	5	6
C	7	8 Columbus Day	9	10	11	12	13
T	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31 Halloween	1	2	3
N	4	5	6 Election Day	7	8	9	10
O	11 Veterans' Day	12	13	14	15	16	17
V	18	19	20	21	22 Thanksgiving	23	24
	25	26	27	28	29	30	1
D	2	3	4	5	6	7	8
E	9 Hanukkah	10	11	12	13	14	15
C	16	17	18	19	20	21	22
	23	24 Christmas Eve	25 Christmas	26	27	28	29
	30	31 New Year's Eve					

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active **in the past 4 weeks. Think about a typical week (7 days).** Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in **7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

j1. During those **7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

No vigorous physical activities



Skip to question 3

j2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about all the **moderate** activities that you did in those **7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

j3. During those **days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

No moderate physical activities



Skip to question 5

j4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about the time you spent **walking** in those **7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

j5. During those **7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

No walking → *Skip to question 7*

j6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the past **7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

j7. During those **7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Vita

Leila Zebin Islam was born in Portsmouth, VA, and is an American citizen. She graduated as valedictorian from Churchland High School in Portsmouth, VA in 1997. She received her Bachelor of Science in Biological Psychology (Neuroscience) as part of an Interdisciplinary Degree program, with a minor in Sociology, from the College of William & Mary in Williamsburg, VA in 2001. She received her Master of Science in Physiology from Virginia Commonwealth University School of Medicine in Richmond, VA in 2003. Leila then worked in the Division of Endocrinology & Metabolism at Virginia Commonwealth University School of Medicine. In 2007, she enrolled in the Clinical Psychology Doctoral Degree program at Virginia Commonwealth University. After completing a clinical internship at the Veterans Affairs Connecticut Healthcare System in West Haven, CT, Leila will graduate in December 2013 with her doctorate in Clinical Psychology.