COGNITIVE TRAINING TO REDUCE IMPULSIVITY IN HIV-INFECTED COCAINE USERS

NCT02909101

Study Protocol with Statistical Analysis Plan

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Specific Aims

This study tests the feasibility and preliminary efficacy of a computerized cognitive training program to improve working memory and decrease impulsivity (delay discounting) among HIV-infected individuals. The specific aims are to

(1) Investigate the effects of the cognitive training intervention on working memory (primary outcome) and delay discounting (secondary outcome) in HIV-infected persons;

(2) Establish the acceptability of computerized cognitive training among HIV-infected past or present cocaine users; and

(3) Examine the effect of cognitive training on HIV risk behaviors, including cocaine use, risky sex, and medication adherence (exploratory outcomes).

We hypothesize that: (1) Participants assigned to active cognitive training (ACT), compared to those in the attention-matched control group (CON), will have greater improvements in working memory and reductions in delay discounting; (2) Participants assigned to ACT, compared to those in CON, will have greater reductions in HIV risk behaviors, including improvements in medication adherence.

Study design

The proposed study will test the efficacy of a cognitive training program to improve working memory in a sample of HIV-infected cocaine users. We will evaluate the effects of this cognitive training intervention on working memory, delay discounting, and HIV risk behaviors. We will first screen participants for eligibility. Eligible participants will be assigned to one of two groups (ACT or CON) and will complete 48 training sessions over 10 weeks. Participants assigned to ACT will complete computerized games designed to enhance working memory, while those assigned to the attention-matched CON will complete games that use other brain attributes. We will be using a web-based program, Lumosity (Lumos Labs, Inc.; http://www.lumosity.com). Lumosity is available to the public and offers user-friendly cognitive training games targeting different brain areas. We have developed a contract with Lumosity tailoring the website to fit our study's needs. All participants will complete assessments at baseline, post-training, and 1-month follow-up to evaluate the impact of the training program. Staff members conducting assessments will be blinded to treatment condition in order to ensure no biases occur during testing.

Eligibility criteria

The sample will be open to HIV-infected men and women aged 18-60 years of all racial/ethnic groups who are currently on antiretroviral medications for >3 months and are cocaine users. Cocaine use will be defined as lifetime regular crack/cocaine use lasting >1 year, cocaine-type stimulant use disorder, and cocaine as the principal substance of abuse. Exclusion criteria will include pregnancy; English non-fluency or illiteracy; ≤ 8th grade education; serious and unstable neurological disorders; unstable serious mental illness or acute psychiatric distress; and impaired mental status. Women who are pregnant will be excluded because of the known effects of pregnancy on neuropsychological functioning (including deficits in memory and executive control). To reduce potential attrition, individuals who state they are planning to move away from the area within the next 3 months and individuals without stable housing will be excluded.

Recruitment

Both clinic- and community-based recruitment strategies will be used. Participants will learn about the study via flyers in clinics, community-based organizations that serve HIV-positive individuals, and participant referrals. Clinic recruitment will occur at local infectious diseases clinics. Patients may also self-refer in response to flyers and brochures displayed in the waiting

area and exam rooms. We may also run advertisements in local newspapers and online. Finally, participants may be recruited through our lab's repository contact database (IRB Pro00047043).

Prescreening

Regardless of how potential participants are informed of the study, interested individuals will complete a pre-screening with a member of the research staff to determine preliminary eligibility. This pre-screening will occur in person or over the telephone.

Cognitive Training Study

Screening Visit. If potentially eligible after prescreening, participants will be invited to complete a 2-3 hour screening visit in our laboratory to verify eligibility criteria. The informed consent process will occur at the beginning of this visit, followed by a breathalyzer to ensure that the participant is not acutely intoxicated. The initial part of the screening visit will include the urine drug testing and pregnancy testing if indicated. Participants will then complete questionnaires and clinical interviews to assess HIV and other medical history, substance use, and mental health (**Table 1**). Trained research assistants will administer clinical interviews and neuropsychological tests of working memory. Additional questionnaires will be administered using audio computer-assisted self-interview (ACASI) technology. The urine toxicology screen will be used to verify self-reports of recent use of cannabis, cocaine, stimulants, opioids, and benzodiazepines.

Table 1. Eligibility Screening Measures

Construct	Instrument(s)
In-person Interview and Testing	
Substance Use & Impairment	Addiction Severity Index-LITE [1,2]
Substance Use Disorders	Structured Clinical Interview for DSM-5 (SCID-5) Module E [3]
Psychiatric history	SCID-5 Modules A and B [3]
HIV Testing and Staging	HIV Cost and Services Utilization Study [4]
Literacy	Wide Range Achiecement Test-4 Word Reading Subtest [5]
ACASI	
Patient Characteristics	Demographics
Anxiety/Depression	Brief Symptom Inventory [6]
HIV Symptoms	HIV Symptoms Index [7]
PTSD Symptoms	Post-Traumatic Stress Disorder Checklist-5 [8]
Craving	Stimulant Craving [9]
Medical History	Veteran's Aging Cohort Study [10]
Trait Impulsivity	Barratt Impulsivity Scale Version 11 [11]
Sensation Seeking	Sensation Seeking Survey Version V [12]

In-person Interview and Testing. In-person interview and testing (lasting approximately 90 minutes) will be conducted by trained research personnel. Interviews will assess substance use and impairment, psychiatric history, HIV testing, staging and treatment history, medication adherence, substance use, sexual behaviors, and psychiatric history.

ACASI. Questionnaires will be programmed using QDS™ software. The computer will display one question at a time, and participants will respond using a mouse. For patients who prefer not to read, the computer will read the questions and responses using prerecorded sound files. The ACASI will last approximately 30 minutes will include items related to demographics, anxiety and depression, HIV symptoms, stimulant craving, and medical history.

Baseline Assessment. Eligible participants will be invited back on a separate day for a 3-hour baseline assessment. At the beginning of this visit, participants will complete a breathalyzer, urine drug testing and pregnancy testing if indicated. Participants will then complete an assessment battery of standardized measures that includes face-to-face interviews, questionnaires, decision making tasks, and neuropsychological testing (**Table 2**).

Neurocognition. A 60-minute comprehensive neuropsychological battery will assess functioning across performance domains and estimates premorbid intellectual functioning. All tests have excellent clinical validity with large national norming samples and will be scored using standard procedures.

In-person interview. Trained research personnel will conduct interviews lasting approximately 30 minutes. The interview will assess HIV medication adherence, substance use, and sexual behaviors.

ACASI. The ACASI will last approximately 40 minutes and will include items related to psychiatric symptoms, food insecurity, stimulant craving, quality of life, smoking history, and sexual and drug risk.

Decision making. Several computerized tasks, lasting approximately 30 minutes, will assess distinct aspects of decision making. The Game of Dice Task (GDT) assesses decision making. In this task, a virtual die is rolled and the participant is asked to select a single number or a combination of two, three, or four numbers. If the number rolled on the die equals any of the numbers in the participant's choice, the participant will gain a specified amount of money in a fictitious bank. The participant will lose an equivalent amount from the fictitious bank if the number rolled is not equal to any of the numbers in their selection. The participant is tasked with accumulating as much money as possible in the bank, and each selection is associated with an explicit gain/loss of fictitious money. The amount of fictitious money that can be gained/lost increases as the probability of the selection occurring decreases. Risky decisions, defined as choices that have less than a 50% chance of occurring, and the frequency of alternative

Table 2. Baseline Measures

Construct	Instrument(s)
In-person Interview	
Medication adherence	ARV Adherence [13,14]
Sex/drug risk	Timeline Follow-back for Substance Use and Sexual Behaviors [15]
HIV Risk Behaviors	HIV Risk Behavior Scale (HRBS) [16]
Neurocognition	
Attention	Conners Continuous Performance Test 3 (CPT 3) [17]
Executive Function	Stroop Color and Word Task [18] Trail Making Test Part B (TMT B) [19]
Learning	Hopkins Verbal Learning Test-Revised (HVLT-R) Immediate [20] Brief Visuospatial Memory Test-Revised (BVMT-R) Immediate [21]
Memory	HVLT-R Delayed [20] BVMT-R Delayed [21]
Processing Speed	Trail Making Test Part A (TMT A) [19] WAIS-IV Coding [22]
Motor	Grooved Pegboard Test (GPT) [23]
Verbal Fluency	Controlled Oral Word Association Test (COWAT; FAS and Animals) [24]
Working Memory	Paced Auditory Serial Addition Test-100 [25] WAIS-IV Letter-Number Sequencing,[22] WAIS-IV Digit Span [22]
Premorbid Functioning	Wechsler Test of Adult Reading (WTAR) [26]
Decision Making	
Decision Making	Game of Dice Task [27]
Delay discounting	Monetary Choice Questionnaire [28]
Abstract reasoning	Wisconsin Card Sorting Test-64 (WCST) [29]
ACASI	
Psychiatric Symptoms	Symptom Checklist 90-Revised (SCL-90) [6]
Food Insecurity	Household Food Insecurity Access Scale [30]
Craving	Stimulant Craving [9]
Quality of Life	World Health Organization Quality of Life-BREF (WHOQOL-BREF) [31]
Self-assessment	Patient's Assessment of Own Functioning Inventory [32]
Sexual/Drug Risk	Risk Assessment Battery (RAB) [33]
Nicotine Dependence	Fagerstrom Test for Nicotine Dependence (FTND) [34] and smoking history
Stimulant Dependence	Severity of Dependence Scale (SDS) [35]

selections will be analyzed. The Monetary-Choice Questionnaire (MCQ) is a delay discounting task. Participants make 36 choices between smaller immediate rewards (ranging from $11 to $78) and larger delayed rewards (ranging from $25 to $85 and from 7 to 186 days). An individual's point of indifference where the perceived value of a smaller immediate reward is equivalent to a larger delayed reward is computed using the following hyperbolic function: $V_{immediate} = V_{delayed}/(1 + kD)$, in which V is value in dollars, D is delay in days, and k is a free parameter that determines the discount rate. The Wisconsin Card Sorting Test-64 (WCST) is used to measure abstract reasoning, concept generation, and perseverative responding. In this computerized task, participants sort cards according to one of three principles of class membership, including categories completed, perseverative responses, perseverative errors, nonperseverative errors, failure to maintain set, and efficiency of learning.

Cognitive Training Sessions. At the end of the baseline assessment, enrolled participants will be randomly assigned to either the experimental (Active Cognitive Training, or ACT) or control (or CON) conditions using simple random assignment. Participants will be trained to use Lumosity after the baseline assessment. Research staff will provide instructions and guide them through the first training session. Participants will then immediately begin completing sessions at home the following day.

Schedule of training sessions*.* All enrolled participants will be asked to complete 48 training sessions over 10 weeks. The sessions will last approximately 20-30 minutes and will be completed at home or wherever the participant can obtain computer access. If the participant has no means of accessing a computer, sessions can be completed in-person in the research laboratory. Participants will be encouraged to complete 6 sessions a week, 1 per day, to reach a total of 48 by the end of the 10-week period. While each group will complete the same number of sessions to control for possible dosage effects, the content of the sessions will vary by study group. Each condition will include 8 unique Lumosity games.

Active Cognitive Training (ACT)*.* Sessions will include games from Lumosity that are designated as targeting working memory. One training session will be comprised of a randomly generated subset of 4 of the 8 working memory games, each played twice back-to-back.

Control Training (CON)*.* The sessions will be in the same format as the ACT group, but will utilize other Lumosity games that do not target working memory. These games will be the same length as the working memory games and participants will complete the same number of randomly generated games per session (4 of the 8 games, played twice back-to-back).

Post-training Assessment*.* After completing the 48th training session, or at the end of the 10-week training window, participants will complete a post-training assessment. This 3-hour visit will occur within 1 week of the final training session and will consist of a battery identical to the baseline assessment. Alternate forms of neuropsychological tests involving memory will be used to avoid effects related to repeated testing. Participants will also complete a process measure to describe their experiences of the intervention and provide feedback on perceived benefits, barriers to completing sessions, and the length, number, and content of sessions. This assessment includes open-ended questions and ratings of satisfaction and helpfulness.

One-month Follow-up Assessment. One month after the post-training assessment, participants will complete a follow-up assessment. This 3-hour visit will consist of a battery identical to the baseline assessment. Alternate forms of neuropsychological tests involving memory will be used to avoid any effects related to repeated testing.

Human Subjects Protections

Rationale for participant selection. The purpose of this study is to examine the impact of cognitive training on neurocognitive performance, including working memory and delay

discounting, on persons with HIV infection and co-occurring cocaine abuse. Therefore, participants will be HIV-positive cocaine users.

Evaluation of benefits, risks, and discomforts. A direct benefit for participants who complete the study may be improved cognitive function as a result of the cognitive training exercises administered at each session. The risk/benefit ratio for this study is relatively low and there are few expected risks associated with participation in this study. All data collection procedures are minimally invasive. All procedures will be performed by research personnel who are trained in the study procedures to minimize risks, discomforts, and adverse events. We expect that the results of this study will inform new treatments for HIV-infected individuals by providing empirical support for a low-cost intervention to improve neuropsychological functioning. Given the minimal amount of risk associated with participation, coupled with the potential scientific gains, we believe that the risk to participants is reasonable.

The potential risks associated with this study fall into the following two categories: confidentiality and emotional distress.

1. Confidentiality. The following precautions will protect the privacy of participants and maintain confidentiality of research data: (1) All staff will be well trained in confidentiality and data security procedures. (2) Privacy will be maintained by conducting all study procedures in closed and soundproof rooms. (3) Each participant will be assigned a unique study ID number, and all data will be de-identified and coded with ID numbers only. The key linking participant names and ID numbers will be stored in a separate password protected document on the secure server maintained by the Department Psychiatry & Behavioral Science, and only essential study staff will have access to it. (4) Data will be securely stored in locked file cabinets in locked offices and in password protected documents on password protected computers and secure servers. Access to data storage areas and computers will be restricted. (5) Analysis will occur on de-identified data only. (6) Data will only be stored for as long as necessary to complete the study, and for adherence to university, hospital, and federal regulations. Thus, while we acknowledge that a breach of confidentiality is possible, the likelihood is very low.

In the event that a subject indicates potential harm to self or others during the research study, this will need to be addressed appropriately and with sensitivity. Any disclosures will be handled within the framework of existing legal mandates, clinical practice, and social norms. Consistent with standard clinical practice, when possible, disclosures will be discussed with the participant to determine the best management alternatives. This may include notifying family members, referring to medical treatment, calling emergency services, or escorting the participant to the Emergency Department at Duke Hospital. When required by law, the Police Department and/or the Department of Social Services will be notified. Dr. Meade (the PI) and Dr. Towe (co-I) are both licensed clinical psychologists with experience managing such cases.

***2. Emotional distress*.** Some participants may experience discomfort or embarrassment related to providing urine samples and answering questions about substance use and other personal behaviors. Participants will be informed prior to the assessment that they may choose to skip any question or procedure they find uncomfortable. All research staff will be extensively trained on study procedures, including the conduct of interviews that elicit personal information, and the importance of being sensitive to and respectful of all participants. If distress does occur, research staff will be trained on how to identify and manage it, and when to terminate an interview. If necessary, the participant will be referred to mental health treatment. It is important to note that, as part of the informed consent procedure, all individuals will be notified that if they express direct threats of harm to self or others, the study team may exercise the right to arrange care or intervention for the individual if the situation is appraised to constitute an emergency.

All project staff will be trained to immediately consult with the PI or back-up person in the event that any applicant or enrolled participant appears to be experiencing psychological or physical distress. Indications of the need for this might include hearing the individual making comments or asking questions that suggest cognitive impairment; noting that the individual appears to be highly anxious, depressed, or withdrawn; or having a belief that the individual may be contemplating harming himself/herself or another person. Responses on select questions (such as the suicide assessment on the SCID assessment) that indicate potential risk of harm to self or others also require immediate consultation. In the event that cases such as this are brought to the PI or back-up person, she will assist the staff member in identifying appropriate community resources and will oversee the process of seeking outside assistance for this individual. Multiple levels of back-up support for research personnel will be developed. The research team includes two licensed clinical psychologists; they will be available to intervene and, when necessary, ensure that appropriate services are received. In the event of clinical deterioration, assessors may perform an initial risk assessment, but any clinical intervention or actions will be conducted by Dr. Meade, Dr. Towe, or a designated back-up person.

Consent processes and documents. Prior to the initiation of any clinical research procedures, designated research staff will describe the study's purpose, all procedures, and risks/benefits and review the informed consent document with the participant. Participants will be provided ample time to read the consent, ask questions, and deliberate their decision. If they choose to participate they will then provide written informed consent. Participants will also sign a release of information form to allow study staff to review their medical record at any other facility where they have obtained HIV and/or other medical care, if applicable. Participants will be given copies of these documents. Participants will provide informed written consent for each of the two parts of the study. These documents will be stored in locked file cabinets in locked offices separate from other data collected in this study.

Compensation. Participants will receive compensation for each of the study visits. Participants may earn up to $441. Participants will be compensated $50 for the screening visit, $75 for the baseline assessment, $65 for the post-training assessment, and $85 for the 1-month follow-up. For the 48 training sessions, participants will be compensated $2 for each completed session, and will earn a bonus after every 6 sessions. Participants will earn a $5 bonus after completing 6, 12, 18, and 24 sessions; a $10 bonus after 30 and 36 sessions; and a $15 bonus after 42 and 48 sessions. Total potential earnings for completing all sessions are $166.

Compensation will be in the form of a reloadable debit card. In addition, we will offer bus tokens (worth $2 for round-trip) or parking passes (worth up to $6) to participants who require assistance.

Safety assessment. Our assessment batteries include several measures intended to assess for safety, including breathalyzer for alcohol intoxication and mental status exam. Adverse events (AEs) will be monitored throughout the study. Each AE will be classified as serious or non-serious, and appropriate reporting procedures will be followed.

Statistical analyses

Initial analyses will confirm the psychometric properties of the assessments, and scale scores will be constructed. Data distributions will be checked to determine if they meet the assumptions of the analytic models, and transformations will be performed when necessary to improve distributional qualities. Preliminary analyses will compare study groups on demographic and other characteristics obtained in the screening and baseline assessments to identify possible failures in random assignment, which would be statistically controlled for in subsequent analyses. We will also test for any differential attrition across groups at both follow-ups. All analyses will be repeated with other substance use added as a covariate.

Hypothesis testing (Aim 1). Using an intent-to-treat analysis, we will investigate the differential impact of condition (ACT vs. CON) at the post-training assessment by performing a 2 (Condition) by 2 (Time) general linear model (GLM) analysis on the main outcome measures of working memory (mean T-score on the 3-test battery) and delay discounting (natural log k-value). Time will be a within subjects factor defined by baseline versus post-training assessment. The analysis will be repeated, adding the 1-month follow-up in a 2 (Condition) by 3 (Time) GLM to detect differential effects of the two conditions on outcomes through the follow-up period. Significant interactions of Condition and Time are predicted. To examine the specificity of the cognitive training intervention, we will use the same models to test for group differences on performance in other cognitive domains (e.g., verbal fluency, processing speed) and other measures of decision making (i.e., contingency learning, risk taking propensity).

Additional analyses will be restricted to participants who were randomized to ACT. First, we will examine predictors of treatment response (moderators) based on sample characteristics. We will use linear regression to predict change in the main outcome variables (working memory and delay discounting), with potential moderators entered separately as predictors. Second, we will use linear regression to evaluate the effect of treatment dosage (number of sessions completed) on change in the outcome variables. Finally, if intervention effects are identified on main outcomes, we will test whether effects were mediated by performance on the working memory training modules using bootstrap analyses.[36-38]

Acceptability (Aim 2). We will examine participant ratings of satisfaction with the cognitive training intervention, as well as their perception of its benefits and barriers to completing sessions. The intervention will be considered acceptable if participant ratings are high (>3.5 on a 5-point scale). We will also calculate the average number of sessions completed and determine the proportion of participants who successfully completed the intervention (defined as completing ≥36 of the 48 total sessions). The intervention will be considered acceptable to the target population if ≥80% complete the intervention.

Exploratory analyses (Aim 3): To investigate the impact of the intervention on risk behaviors, we will use the same GLM models described above to test for differences by condition on cocaine use (number of days of use), sexual risk (HRBS sex risk score), and adherence to ARVs (percent medication adherence).

Clinical Trials Registration

This study is registered at http://www.ClinicalTrials.gov (Identifier: NCT: NCT02909101).

References

1. McLellan AT, Kushner H, Metzger D, et al. The fifth edition of the Addiction Severity Index. *J Subst Abuse Treat.* 1992;9(3):199-213.
2. McGahan PL, Griffith JA, Parente R, McLellan AT. *Addiction Severity Index Composite Scores Manual* Philadelphia: The University of Pennsylvania/Veterans Administration Center for Studies of Addiction; 1986.
3. First MB, Williams JBW, Karg RS, Spitzer RL. *Structured Clinical Interview for DSM-5-Research Version (SCID-5 for DSM-5, Research Version; SCID-5-RV).* Arlington, VA: American Psychiatric Association; 2015.
4. RAND Corporation. *HIV Cost and Services Utilization Study (HCSUS) baseline questionnaire.* Santa Monica, CA: RAND Corporation; 2007.
5. Wilkinson GS, Robertson GJ. *Wide Range Achievement Test–4 (WRAT-4).* Lutz, FL: Psychological Assessment Resources.
6. Derogatis LR. *Brief Symptom Inventory: Administration, Scoring, and Procedures Manual.* 3rd ed. Minneapolis, MN: National Computer Systems, Inc.; 1993.
7. Justice AC, Holmes W, Gifford AL, et al. Development and validation of a self-completed HIV symptom index. *J Clin Epidemiol.* 2001;54(Suppl 1):S77-S90.
8. Blevins CA, Weathers FW, Davis MT, Witte TK, Domino JL. The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and Initial Psychometric Evaluation. *J Traum Stress.* 2015;28(6):489-498.
9. Weiss RD, Griffin ML, Hufford C, et al. Early prediction of initiation of abstinence from cocaine: use of a craving questionnaire. *American Journal of Addictions.* 1997;6:224-231.
10. Smola S, Justice AC, Wagner J, Rabeneck L, Weissman S, Rodriguez-Barradas M. Veterans aging cohort three-site study (VACS 3): overview and description. *J Clin Epidemiol.* 2001;54(Suppl 1):S61-76.
11. Patton JH, Stanford MS, Barratt ES. Factor structure of the Barratt Impulsiveness Scale. *J Clin Psychol.* 1995;51(6):768-774.
12. Zuckerman M. *Behavioral Expressions and Biosocial Bases of Sensation Seeking.* Cambridge: Cambridge University Press; 1994.
13. Giordano TP, Guzman D, Clark R, Charlebois ED, Bangsberg DR. Measuring adherence to antiretroviral therapy in a diverse population using a visual analogue scale. *HIV Clinical Trials.* 2004;5(2):74-79.
14. Kalichman SC, Amaral CM, Swetzes C, et al. A simple single-item rating scale to measure medication adherence: further evidence for convergent validity. *Journal of the International Association of Physicians in AIDS Care.* 2009;8(6):367-374.
15. Sobell LC, Sobell MB. *Timeline Follow-back User's Guide: A Calendar Method for Assessing Alcohol and Drug Use.* Toronto: Addiction Research Foundation; 1996.
16. Darke S, Hall W, Heather N, Ward J, Wodak A. The reliability and validity of a scale to measure HIV risk-taking among intravenous drug users. *AIDS.* 1991;5(2):181-185.
17. Conners CK. *Conners Continuous Performance Test 3rd Edition.* Toronto, Canada: Multi-Health Systems; 2014.
18. Golden CJ. *Stroop Color and Word Test.* Chicago, IL: Stoelting; 1978.
19. Lezac MD. *Neuropsychological assessment (3rd Edition).* New York: Oxford University Press; 1995.
20. Brandt J, Benedict RHB. *Hopkins Verbal Learning Test -- Revised professional manual.* Lutz, FL: Psychological Assessment Resources, Inc; 2001.
21. Benedict RHB, Schretlen D, Groninger L, Dobraski M. Revision of the Brief Visuospatial Memory Test: studies of normal performance, reliability, and validity. *Psychological Assessment.* 1996;8(2):145-153.

22. Wechsler D. *Wechsler Adult Intelligence Scale--Fourth Edition: Administration and Scoring Manual.* Bloomington, MN: Pearson; 2008.
23. Heaton RK, Grant I, Matthews CG. *Comprehensive Norms for an Expanded Halstead-Reitan Battery: Demographic Corrections, Research Findings, and Clinical Applications.* Odessa, FL: Psychological Assessment Resources; 1991.
24. Benton A, Hamsher K, Sivan A. *Multilingual Aphasia Examination (3rd ed.).* Iowa City, IA: AJA Associates; 1983.
25. Diehr MC, Cherner M, Wolfson TJ, Miller SW, Grant I, Heaton RK. The 50 and 100-item short forms of the Paced Auditory Serial Addition Task (PASAT): Demographically corrected norms and comparisons with the full PASAT in normal and clinical samples. *J Clin Exp Neuropsychol.* 2003;25(4):571-585.
26. Wechsler D. *Wechsler Test of Adult Reading (WTAR) Manual.* San Antonio, TX: Harcourt Assessment; 2001.
27. Brand M, Fujiwara E, Borsutzky S, Kalbe E, Kessler J, Markowitsch HJ. Decision-making deficits of korsakoff patients in a new gambling task with explicit rules: associations with executive functions. *Neuropsychology.* 2005:267-277.
28. Kirby KN, Petry NM, Bickel WK. Heroin addicts have higher discount rates for delayed rewards than non-drug-using controls. *J Exp Psychol Gen.* 1999;128(1):78-87.
29. Kongs SK, Thompson LL, Iverson GL, Heaton RK. *Wisconsin Card Sorting Test-64 Computerized Version.* Odessa, FL: Psychological Assessment Resources; 2000.
30. Kalichman SC, Cherry C, Amaral C, et al. Health and treatment implications of food insufficiency among people living with HIV/AIDS, Atlanta, Georgia. *J Urban Health.* 2010;87(4):631-641.
31. Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. *Qual Life Res.* 2004;13(2):299-310.
32. Chelune GJ, Heaton RK, Lehman RA. *Neuropsychological and Personality Correlates of Patients Complaints of Disability.* New York: Plenum Press; 1986.
33. Metzger DS, Nalvaline HA, Woody GE. Assessment of substance abuse: HIV risk assessment battery. In: Carson-Dewitt R, ed. *Encyclopedia of Drugs, Alcohol, and Addictive Behavior.* 1st ed. Framington Hills, MI: Macmillan Reference USA; 2001.
34. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict.* 1991;86(9):1119-1127.
35. Churchill AC, Burgess PM, Pead J, Gill T. Measurement of the severity of amphetamine dependence. *Addiction.* 1993;88(10):1335-1340.
36. Preacher KJ, Hayes AF. SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behavioral Research Methods, Instruments, and Computers.* 2004;36(4):717-731.
37. MacKinnon DP, Lockwood CM, Williams J. Confidence limits for the indirect effect: distribution of the product and resampling methods. *Multivariate Behavioral Research.* 2004;39(1):99.
38. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *J Pers Soc Psychol.* 1996;51(6):1173-1182.