Statistical Analysis Plan: Work2Prevent – Phase 2

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ATN	Adolescent Medicine Trials Network for HIV/AIDS Interventions
CAI	Condomless Anal Intercourse
CC	ATN Coordinating Center
CSCC	Collaborative Studies Coordinating Center
HIV	Human Immunodeficiency Virus
HQ	Handbook Quality
IQ	Information Quality
ISSM	Information Systems Success Model
JSS	Job-Seeking Self-Efficacy
MSM	Men who have Sex with Men
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
PCA	Protean Career Attitudes
PU	Perceived Usefulness
SDA	Self-Directed Attitudes
STI	Sexually Transmitted Infection
T1	Baseline Visit
T2	Post-Intervention Visit at 0-2 weeks post-intervention
T3	Follow-up at 8-months (±4 weeks) post-intervention
VDA	Values-Driven Attitudes
W2P	Work2Prevent
YMSM	Young Men who have Sex with Men
YTW	Young Transgender Women

1. INTRODUCTION

Work2Prevent (W2P) is a project designed to adapt, tailor, and pilot-test a novel social and structural-level HIV intervention for Young Men who have Sex with Men (YMSM) and Young Transgender Women (YTW) of color aimed at increasing economic stability (i.e., employment) through youth empowerment and asset development, and decreasing HIV risk behaviors (i.e., sex work) associated with social and economic marginalization. This document gives details of the planned statistical analysis for Phase 2 of the intervention.

1.1. Objectives and Research Hypotheses

The primary objective of Phase 2 is to pilot-test the intervention among up to 70 at-risk YMSM and YTW of color in order to evaluate feasibility and acceptability. Investigators hypothesize the intervention will increase job self-efficacy and readiness, as well as decrease HIV risk behaviors and STI and HIV infections.

2. STUDY METHODS

2.1. Study Design

W2P is a single-arm longitudinal pre and post study of the social and structural-level employment intervention to evaluate feasibility, acceptability, and satisfaction of the intervention program, and preliminary efficacy for study outcomes assessed at Baseline (T1), Post-Intervention (T2, 0 to 2 weeks post workshop completion), and 8-Month Follow-up (±4 weeks) (T3). The study employment intervention is comprised of four structured workshops presented over a 2-week period.

The study aims to enroll up to 70 at-risk YMSM and YTW of color over a 6-month period. The intervention workshops will be completed within 12 weeks of enrollment. Each participant will then be assessed 8-months (±4 weeks) post-intervention.

Study outcomes include: (1) Job self-efficacy and readiness; (2) HIV risk behaviors; (3) Employment; and (4) STI and HIV infections.

2.2. Study Population

All intervention study participants are Black or African American or Hispanic or Latinos males, including transgender women (those assigned male at birth), ages 16-24, who identify as either an (1) MSM or gay or bisexual man or as a (2) transgender woman or transsexual male-to-female or transwoman.

Participant Inclusion Criteria[1]:

1. Being male or assigned male at birth (YTW)
2. Identifying as YMSM or gay bisexual man or transgender woman or transwoman
3. Identifying as African American or Black, Hispanic or Latino, or as a racial or ethnic minority or person of color
4. 16-24 years old
5. English-speaking (primary)
6. HIV negative or of unknown status
7. Currently unemployed but seeking employment, or employed only part-time (average of 35 hours or less per week)
8. Able to attend a 4-session employment program

Participant Exclusion Criteria:

1. Individuals identifying as non-Hispanic white
2. Individuals not assigned male at birth

2.3. Sample Size Information

This study aims to enroll up to 70 participants with at least 50 of these participants completing the study (~70% retention rate). Given the exploratory nature of this study and limited access to this population, a power calculation was not performed. A repeated measures design was chosen to reduce the variability in the estimate of the treatment effect, at the expense of having a comparison group. In addition, practice or fatigue effects from repetition may affect certain outcomes (e.g. protean career attitudes scale and subscales). This trade-off was appropriate given the exploratory nature of a pilot study and the limited access to the study population.

3. ANALYSIS POPULATIONS

Only participants who are enrolled at Baseline (complete the T1 survey) will be included in the primary and secondary analyses. Screen-failures will not be included in these analyses.

3.1. Intent-to-Treat Population

All participants who completed T3 will be included in intent-to-treat analyses involving variables measuring changes from T1 to T3 (see sections 4.1.3-4.1.4 and 4.2.1-4.2.5 below).

All participants who completed at least one workshop will be included in intent-to-treat analyses involving workshop evaluation and workshop completion variables (see sections 4.1.1,

[1] The original inclusion criteria included "Considered 'at-risk' for HIV based on 6-item risk assessment". The removal of this criterion was approved on August 16, 2018 as part of protocol v4.0 and eligibility was rerun retrospectively for those who completed the Screener Survey (SCR) prior to the inclusion criteria modification.

4.1.2 below). This population will form the basis for both the primary and secondary analyses of the efficacy and safety endpoints.

3.2. Per Protocol Population

Youth who attend at least two of the four planned intervention workshops and complete T3 will comprise the per protocol population. This population will form the basis for both the primary and secondary supportive analyses of the efficacy and safety endpoints.

4. STUDY ASSESSMENTS

Study Assessments	Pre-Screening	Baseline (T1)	Post-Intervention (T2)	8-Month Follow-Up (T3)
Screener Questionnaire (SCR)	X			
Eligibility Form (ELG)		X		
Baseline Questionnaire (BSL)		X		
Biospecimen Collection Form (BIC)		X		X
Biospecimen Lab Results Form (BLR)		X		X
Workshop Tracking (WTI)			X	
Workshop Evaluation (EVL)			X	
Exit Visit Questionnaire (EXQ)				X

4.1. Primary Outcomes

4.1.1. Information Systems Success Model Score (T2)

The Information Systems Success Model (ISSM) will be used to assess for intervention acceptability and satisfaction. The 21-item scale measures four sub-domains: information quality, handbook quality, perceived usefulness, and overall satisfaction. Every item is scored on a 1 to 5 scale, with 1 being “Strongly Disagree” and 5 being “Strongly Agree”. Responses are averaged within each sub-domain to produce four sub-domain scores. The four sub-domain scores are then averaged to produce an overall ISSM score (range: 1 to 5; higher scores indicate higher acceptability/satisfaction). This scale has been adapted from Horvath et al.[1]

4.1.2. Workshop Completion (T2)

Workshop completion will be used to assess for intervention feasibility. The outcome of intervention completion will be defined as having attended at least two of the four workshop sessions and will be measured by tracking participant attendance. Workshop completion may also be defined as the number of workshop sessions attended for use in exploratory analyses.

4.1.3. Change in Job-Seeking Self-Efficacy Scale Score (T1 to T3)

Job seeking self-efficacy is defined as one's perceived ability and confidence to perform job search and application activities. The 12-item Job Seeking Self-Efficacy (JSS) scale by Barlow et al[2] uses response values on a 1 to 10 score, with 1 being "Not At All Confident" and 10 being "Very Confident". Reponses are averaged to yield a total score, with higher scores indicating higher self-efficacy. Change in JSS will be calculated by subtracting the JSS score at baseline (T1) from the JSS score at the 8-month follow-up (T3) (range: -9 to +9; negative change indicates decreased self-efficacy, while positive change indicates increased self-efficacy).

4.1.4. Change in Protean Career Attitudes Scale Score (T1 to T3)

Protean career attitudes (PCAs) are defined as having self-direction in the pursuit of success in one's work. PCAs have previously been found to be associated with positive career satisfaction and self-perceived success.[3] The validated 7-item scale by Porter et al[4] measures two sub-domains: self-directed attitudes and values-driven attitudes. Every item is scored on a 1 to 5 scale, with 1 being "Strongly Disagree" and 5 being "Strongly Agree". Responses are averaged within each sub-domain to produce two sub-domain scores, which are then averaged as well to produce an overall PCA score. Change in PCA score will be calculated by subtracting the score at baseline (T1) from the score at the 8-month follow-up (T3) (range: -4 to +4; negative change indicates decreased PCAs, while positive change indicates increased PCAs).

4.2. Secondary Outcomes

4.2.1. Change in Self-Reported Hours Worked Per Week (T1 to T3)

Hours worked per week will be self-reported at baseline and at the 8-month follow-up visit as any value between 0 and 99. Change in hours worked per week will be calculated by subtracting the baseline (T1) value from the 8-month follow-up (T3) value. Negative change indicates fewer hours worked per week, while positive change indicates more hours work per week.

4.2.2. Change in Self-Reported Sexual Risk Behaviors (T1 to T3)

Sexual risk behaviors will be measured using six yes or no (1 or 0) items assessing for engagement in the following behaviors during the 6 months prior to baseline (T1) and 8-month follow-up (T3) assessments:

1. condomless anal intercourse (CAI) with male partner of unknown HIV status
2. anal intercourse with ≥3 males
3. sex with male partner with a Sexually Transmitted Infection (STI)
4. CAI with HIV+ male partner
5. anal intercourse with condom failure
6. transactional sex work involvement

Responses will be averaged at each assessment. Change in sexual risk behaviors will be calculated by subtracting the average at baseline from the average at the 8-month follow-up (range: -1 to +1; negative change indicates fewer sexual risk behaviors, while positive change indicates more sexual risk behaviors).

4.2.3. Change in Chlamydia Test Result (T1 to T3)

Chlamydia infections will be assessed at baseline and 8-month follow up using oral, anal, and urine samples. Each of the three tests yields a positive (1) or negative (0) result. Change in test result will be calculated by subtracting the baseline result from the 8-month follow-up result. Oral, anal, and urine tests will be treated as separate outcomes.

4.2.4. Change in Gonorrhea Test Result (T1 to T3)

Gonorrhea infections will be assessed at baseline and 8-month follow up using oral, anal, and urine samples. Each of the three tests yields a positive (1) or negative (0) result. Change in test result will be calculated by subtracting the baseline result from the 8-month follow-up result. Oral, anal, and urine tests will be treated as separate outcomes.

4.2.5. Reactive HIV Test (T3)

Testing for HIV will be assessed at baseline and 8-month follow up. The test yields a reactive (1) or non-reactive (0) result. The outcome for reactive HIV test will use the T3 test result.

5. STATISTICAL ANALYSIS

5.1. General Considerations

The analytic plan is designed to determine preliminary efficacy of the intervention by comparing pre/post assessments of employment and sexual risk behaviors. Descriptive statistics will be used to analyze the proportions and central tendencies for participant sociodemographic covariates collected in the surveys. We will first generate frequencies, means, and other measures of central tendency as appropriate to describe our sample and outcomes at each of the three time points (baseline, post-intervention, and 8-month follow-up).

Changes in primary and secondary outcomes between baseline and 8-month follow-up will be assessed using paired t-tests for continuous variables and McNemar's test for matched categorical variables. We will use standard diagnostic tools to assess the appropriateness of the normality assumption (e.g., QQ-plots) and, if approximate normality of the residuals is not tenable, a non-parametric test for continuous paired data, i.e. Wilcoxon sign rank test will be used. All hypothesis testing will be done at an alpha-level of 0.1, given the exploratory nature of the study.

5.2. Missing Data

Missing responses to survey questions will be ignored and non-missing data will be used to compute the primary and secondary outcomes. If all components for an outcome are missing, then the outcome will be considered missing. For those outcomes with unique missing data rules, the handling of missing data for each individual outcome are described in the appendix. Missing data patterns will be explored prior to the analysis of the primary and secondary outcomes.

5.3. Subject Disposition Analyses

Number of participants pre-screened, screened, eligible, discontinued, and included in the Per Protocol analysis population will be reported. In addition, the number of participants completing each visit (T1, T2 and T3) and the reasons for patient discontinuation will be tabulated.

5.4. Analysis of Primary Outcomes

Primary outcomes for analyses include Information Systems Success Model score, workshop completion, change in Job-Seeking Self Efficacy Scale score, Protean Career Attitudes Scale score, change in Self-Directed Attitudes Scale score, and change in Values-Driven Attitudes Scale score. Details about these outcomes are described in Section 4.1.

Univariate analyses will be performed as described in Section 5.1. To the extent that data allows, multivariable analyses will adjust for sociodemographic characteristics, workshop attendance, baseline employment status, and study completeness. Analytical models will include linear regression or generalized linear models for continuous outcomes and logistic regression for binary and categorical outcomes.

5.5. Analysis of Secondary Outcomes

Secondary outcomes for analyses include change in self-reported hours worked per week, change in self-reported sexual risk behavior, change in chlamydia test results, change in gonorrhea test results, and reactive HIV test result. Details about these outcomes are described in Section 4.2.

Univariate analyses will be performed as described in Section 5.1. Multivariable analyses will adjust for sociodemographic characteristics, workshop attendance, baseline employment status, and study completeness. Analytical models will include linear regression or generalized linear models for continuous outcomes and logistic regression for binary and categorical outcomes.

5.6. Analysis of Safety Events

Safety Events will be recorded for participants as needed throughout the study. The number of participants experiencing each safety event will be summarized by severity grade, relationship

to study, and action taken. All safety events will be provided in the safety events data listing. Withdrawals due to safety events will also be reported.

REFERENCES

1. Horvath KJ, Oakes MJ, Rosser SBR, Danilenko G, Vezina H, Amico RK, Williams ML, Simoni J. *Feasibility, Acceptability and Preliminary Efficacy of an Online Peer-to-Peer Social Support ART Adherence Intervention.* AIDS Behav., 2013; 17:2031-2044.

2. Barlow J, Wright C, Cullen L. *A job-seeking self-efficacy scale for people with physical disabilities: preliminary development and psychometric testing.* Br J Guid Counc., 2002; 30:1, 37-53.

3. Volmer J, Spurk D. *Protean and boundaryless career attitudes: relationships with subjective and objective career success.* J Labor Mark Res., 2011; 43:207-218.

4. Porter C, Woo SE, Tak J. *Developing and Validating Short Form Protean and Boundaryless Career Attitudes Scales.* J Career Assess., 2016; 24(1):162-181.

APPENDIX

1. PRIMARY OUTCOMES

1.1. INFORMATION SYSTEMS SUCCESS MODEL (ISSM) SCALE

The Information Systems Success Model (ISSM) scale has been adapted from Horvath et al. 2013 to assess intervention acceptability and satisfaction. The scale evaluates four sub-domains: information quality, system quality, perceived usefulness, and overall satisfaction. For each of the calculated scores, higher values indicate better participant-assessed quality.

1.1.1. ISSM Subscale 1: Information Quality (IQ) Score

Description: Information Quality is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate ease of comprehension, credibility, clarity, and accuracy of the information provided through the intervention using responses to items 7a through 7e and 8a in the Evaluation (EVL) Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: IQ_T2_1

Label: Information Quality Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: IQ_T2_1 = MEAN (EVL7a, EVL7b, EVL7c, EVL7d, EVL7e, EVL8a)

If all responses are missing, then then IQ_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.2. ISSM Subscale 2: Handbook Quality (HQ) Score

Description: Handbook Quality is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate user friendliness and appeal of the workshop handbook provided through the intervention using responses to items 8b through 8e, 9a, and 9b in the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: HQ_T2_1

Label: Handbook Quality Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: HQ_T2_1 = MEAN (EVL8b, EVL8c, EVL8d, EVL8e, EVL9a, EVL9b)

If all responses are missing, then HQ_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.3. ISSM Subscale 3: Perceived Usefulness (PU) Score

Description: Perceived Usefulness is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate the usefulness of the intervention to help the participant to achieve their career-related goals using responses to items 6c, 9c through 9e, 10a, and 10b in the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: PU_T2_1

Label: Perceived Usefulness Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: PU_T2_1 = MEAN (EVL6c, EVL9c, EVL9d, EVL9e, EVL10a, EVL10b)

If all responses are missing, then PU_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.4. ISSM Subscale 4: Overall Score

Description: The Overall Score is a 3-item sub-scale measured at time point T2 (post-intervention) to evaluate the overall satisfaction with the workshops using responses to items 10c through 10e from the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: OVERALL_T2_1

Label: Overall Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: OVERALL_T2_1 = MEAN (EVL10c, (6 - EVL10d), EVL10e)

If all responses are missing, then OVERALL _T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.5. Information Systems Success Model (ISSM) Score

Description: The ISSM Score is obtained by adding the four subscale scores defined above: IQ Score, HQ Score, PU Score, and Overall Score.

Variable: ISSM_T2_1

Label: Information Systems Success Model Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: ISSM_T2_1 = MEAN (IQ_T2_1, HQ_T2_1, PU_T2_1, OVERALL_T2_1).

If all responses are missing, then ISSM_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.2. WORKSHOP COMPLETION

Workshop completion will be used in the assessment of intervention feasibility. The primary outcome for workshop completion will be measured using a binary outcome of Complete vs. Not Complete (1.2.2), but the number of completed workshops (1.2.1) is also defined to assess potential dose response of the workshop intervention on other outcomes.

1.2.1. Number of Workshops Attended

Description: The participants' workshop attendance is recorded in items 3a, 3c, 4a, 4c, 5a, 5c, 6a, and 6c of the Workshop Tracking Information (WTI) form.

Variable: WSATTEND_T2_1

Label: Number of Workshops Attended at T2

Type: Numeric; Range = 0 to 4

Algorithm: WSATTEND_T2_1 = SUM (WTI3a, WTI3c, WTI4a, WTI4c, WTI5a, WTI5c, WTI6a, WTI6c)

If all responses are missing, then WSATTEND_T2_1=Missing. Otherwise, sum non-missing responses. Note: WTI#c can only have a response if WTI#a=0.

1.2.2. Workshop Completion

Description: Workshop completion is defined as having attended at least two of the four workshop sessions (50% completion).

Variable: WSCOMP_T2_1

Label: Workshop Completion at T2

Type: Numeric; Format: 0=Not Complete, 1=Complete, .=Missing

Algorithm: If WSATTEND_T2_1 >= 2 then WSCOMP_T2_1 = 1
Else if WSATTEND_T2_1 in (0, 1) then WSCOMP_T2_1=0
Else WSCOMP_T2_1 = .

1.3. JOB SEEKING SELF-EFFICACY SCALE SCORE

Job seeking self-efficacy is defined as one's perceived ability and confidence to perform job search and application activities. Higher values indicate higher self-efficacy. This scale is measured at Baseline (T1) and the Month 8 Follow-up (T3).

1.3.1. Job Seeking Self-Efficacy Score at Baseline (T1)

Description: Job Seeking Self-Efficacy score at time point T1 (Baseline) is based on 12 items (52a through 52f and 53a through 53f) from the BSL Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T1_1

Label: Job-Seeking Self Efficacy Score at T1

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T1_1 = MEAN(BSL52a, BSL52b, BSL52c, BSL52d, BSL52e, BSL52f, BSL53a, BSL53b, BSL53c, BSL53d, BSL53e, BSL53f)

If all responses are missing, then JOBSEEK_T1_1=Missing. Otherwise, calculate the mean of the non-missing responses.

1.3.2. Job Seeking Self-Efficacy Score at Post-Intervention (T2)

Description: Job Seeking Self-Efficacy score at time point T2 (Post-Intervention) is based on 12 items (13a through 13f and 14a through 14f) from the EVL Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T2_1

Label: Job-Seeking Self Efficacy Score at T2

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T2_1 = MEAN (EVL13a, EVL13b, EVL13c, EVL13d, EVL13e, EVL13f, EVL14a, EVL14b, EVL14c, EVL14d, EVL14e, EVL14f)

If all responses are missing, then JOBSEEK_T2_1=Missing. Otherwise, calculate the mean of the non-missing responses.

1.3.3. Job Seeking Self-Efficacy Score at Month 8 Follow-Up (T3)

Description: Job Seeking Self-Efficacy score at time point T3 (Month 8 follow-up) is based on 12 items (52a through 52f and 53a through 53f) from the EXQ Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T3_1

Label: Job-Seeking Self Efficacy Score at T3

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T3_1 = MEAN (EXQ52a, EXQ52b, EXQ52c, EXQ52d, EXQ52e, EXQ52f, EXQ53a, EXQ53b, EXQ53c, EXQ53d, EXQ53e, EXQ53f)

If all responses are missing, then JOBSEEK_T3_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.3.4. Change in Job Seeking Self-Efficacy Score from Baseline to Month 8 Follow-Up (T1T3)

Description: Difference between Job Seeking Self-Efficacy score at the Month 8 follow-up (T3) and the score at Baseline (T1). If the Job Seeking Self-Efficacy score is missing at T3, then the score from T2 is used to compute the change in score from T1.

Variable: JOBSEEK_T1T3_1

Label: Change in Job-Seeking Self Efficacy Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -9 to 9

Algorithm: If JOBSEEK_T3_1 not . then JOBSEEK_T1T3_1=JOBSEEK_T3_1 – JOBSEEK_T1_1
Else if JOBSEEK_T3_1=. then JOBSEEK_T1T3_1=JOBSEEK_T2_1 – JOBSEEK_T1_1

If JOBSEEK_T1_1 is missing, then JOBSEEK_T1T3_1=Missing. If JOBSEEK_T2_1 and JOBSEEK_T3_1 are missing, then JOBSEEK_T1T3_1=Missing.

1.4. PROTEAN CAREER ATTITUDES SCALE (PCA) SCORE:

Protean career attitudes are defined as having self-direction in the pursuit of success in one's work. The scale (and the two sub scales) were measured at Baseline (T1) and the Month 8 follow-up (T3). Higher values indicate better attitudes.

1.4.1. PCA Subscale 1: Self-Directed Attitudes Scale Score

1.4.1.1. Self-Directed Attitudes Score at Baseline (T1)

Description: Self-directed Attitudes Scale Score at time point T1 (Baseline) is based on four items (75b, 75c, 75d, and 76a) from the BSL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: SDA_T1_1

Label: Self-Directed Attitudes Scale Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: SDA_T1_1 = MEAN (BSL75b, BSL75c, BSL 75d, BSL76a)

If all responses are missing, then SDA_T1_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.4.1.2. Self-Directed Attitudes Score at Month 8 Follow-Up (T3)

Description: Self-directed Attitudes Scale Score at time point T3 (Month 8 follow-up) is based on four items (75b, 75c, 75d, and 76a) from the EXQ Questionnaire. Responses are recorded as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: SDA_T3_1

Label: Self-Directed Attitudes Scale Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: SDA_T3_1 = MEAN (EXQ75b, EXQ75c, EXQ75d, EXQ76a)

If all responses are missing, then SDA_T3_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.4.1.3. Change in Self-Directed Attitudes Score from Baseline to Month 8 Follow-Up (T1T3)

Description: Difference between Self-Directed Attitudes score at time point T3 (Month 8 follow-up) and time point T1 (Baseline)

Variable: SDA_T1T3_1

Label: Change in Self-Directed Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: SDA_T1T3_1 = SDA_T3_1 – SDA_T1_1

If SDA score at either time point is missing, then SDA_T1T3_1=Missing.

1.4.2. PCA Subscale 2: Values-Driven Attitudes Scale Score

1.4.2.1. Values-Driven Attitudes (VDA) Score at Baseline (T1)

Description: Values driven Attitudes Scale Score at time point T1 (Baseline) is based on 3 items (76b, 76c, and 76d) from the BSL Questionnaire. Response are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: VDA_T1_1

Label: Values-Driven Attitudes Scale Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: VDA_T1_1 = MEAN (BSL76b, BSL76c, BSL76d)

If all responses are missing, then VDA_T1_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.4.2.2. Values-Driven Attitudes (VDA) Score at Month 8 Follow-Up (T3)

Description: Values driven Attitudes Scale Score at time point T3 (Month 8 follow-up) is based on 3 items (76b, 76c, and 76d) from the EXQ Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points

Variable: VDA_T3_1

Label: Values-Driven Attitudes Scale Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: VDA_T3_1 = MEAN (EXQ76b, EXQ76c, EXQ76d)

If all responses are missing, then VDA_T3_1=Missing. Otherwise, calculate the mean ofnon-missing responses.

1.4.2.3. Change in Values-Driven Attitudes (VDA) Score from Baseline to Month 8 Follow-Up (T1T3)

Description: Difference between Values-Driven Attitudes Score at time point T3 (Month 8 follow-up) from time point T1 (Baseline)

Variable: VDA_T1T3_1

Label: Change in Values Driven Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: VDA_T1T3_1 = VDA_T3_1 – VDA_T1_1

If VDA score at either time point is missing, then VDA_T1T3_1=Missing.

1.4.3. Scale: Protean Career Attitudes (PCA) Scale

1.4.3.1. Protean Career Attitudes (PCA) Score at Baseline (T1)

Description: The Protean Career Attitudes Score at T1 is obtained by adding the two subscale scores defined above: SDA Score at T1 and VDA Score at T1.

Variable: PCA_T1_1

Label: Protean Career Attitudes Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: PCA_T1_1 = MEAN (SDA_T1_1, VDA_T1_1)

If either SDA or VDA score is missing, then PCA_T1_1=Missing.

1.4.3.2. Protean Career Attitudes (PCA) Score at Month 8 Follow-Up (T3)

Description: The Protean Career Attitudes Score at T3 is obtained by adding the two subscale scores defined above: SDA Score at T3 and VDA Score at T3.

Variable: PCA_T3_1

Label: Protean Career Attitudes Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: PCA_T3_1 = MEAN (SDA_T3_1, VDA_T3_1)

If either SDA or VDA score is missing, then PCA_T3_1=Missing.

1.4.3.3. Change in Protean Career Attitudes (PCA) Score from Baseline to Month 8 Follow-Up (T1T3)

Description: Difference between protean career attitudes score at time point T3 (Month 8 follow-up) and time point T1 (Baseline)

Variable: PCA_T1T3_1

Label: Change in Protean Career Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: PCA_T1T3_1 = PCA_T3_1 – PCA_T1_1.

If PCA score at either time point is missing, then PCA_T1T3_1=Missing.

2. SECONDARY OUTCOMES

2.1. SELF-REPORTED EMPLOYMENT

The primary employment outcome is based on the change in the number of self-report hours worked per week from T1 to T3.

2.1.1. Change in Self-Reported Hours Worked Per Week from Baseline to Month 8 Follow-Up (T1T3)

Description: Change in hours worked per week from Baseline to Month 8 follow-up (T1 to T3)

Variable: EMPHOUR_T1T3_1

Label: Change in Hours Worked per Week from T1 to T3 (T3-T1)

Type: Numeric; Range = -99 to 99

Algorithm: If BSL9 = 0 then BSL27 = 0
If EXQ9 = 0 then EXQ27 = 0
EMPHOUR_T1T3_1 = EXQ27 – BSL27

If hours work per week at either time point is missing, then EMPHOUR_T1T3_1=Missing.

2.2. SELF-REPORTED SEXUAL RISK BEHAVIORS

2.2.1. Self-Reported Sexual Risk Behavior at Baseline (T1)

Description: Sexual Risk behavior is measured using items 239 through 244 from the BSL Questionnaire. Responses for each question are either Yes (1), No (0) or Missing (.). Risk Behavior is defined as the mean of responses to the risk behavior questions.

Variable: RISK_T1_1

Label: Self-Reported Sexual Risk Behavior at T1

Type: Numeric; Range = 0 to 1

Algorithm: RISK_T1_1 = MEAN (BSL239, BSL240, BSL241, BSL242, BSL243, BSL244)

If responses for four or more individual risk behavior questions are missing, then RISK_T1_1 = Missing. Otherwise, calculate the mean of non-missing responses.

2.2.2. Self-Reported Sexual Risk Behavior at Baseline (T3)

Description: Sexual Risk behavior is measured using items 239 through 244 from the EXQ Questionnaire. Responses for each question are either Yes (1), No (0) or Missing (.). Risk Behavior is as the mean of responses to the risk behavior questions.

Variable: RISK_T3_1

Label: Self-Reported Sexual Risk Behavior at T3

Type: Numeric; Range = 0 to 1

Algorithm: RISK_T3_1 = MEAN (EXQ239, EXQ240, EXQ241, EXQ242, EXQ243, EXQ244)

If responses for four or more individual risk behavior questions are missing, then RISK_T3_1 = Missing. Otherwise, calculate the mean of non-missing responses.

2.2.3. Change in Self-Reported Risk Behavior from Baseline to Month 8 Follow-Up (T1T3)

Description: Change in Self-Reported Risk Behavior of a participant from Baseline to month 8 follow-up (T1 to T3)

Variable: RISK_T1T3_1

Label: Change in Self-Reported Sexual Risk Behavior from T1 to T3 (T3-T1)

Type: Numeric; Range = -1 to 1

Algorithm: RISK_T1T3_1 = RISK_T3_1 – RISK_T1_1.

If risk behavior at either time point is missing, then RISK_T1T3_1 = Missing.

2.3. CHLAMYDIA INFECTIONS:

Chlamydia will be assessed at T1 (Baseline) and T3 (8-month follow-up) using urine, anal, and oral sample tests.

2.3.1. Chlamydia Result at Baseline (T1)

2.3.1.1. Chlamydia Result based on Oral Sample at T1

Description: The oral sample collection status is recorded in item 10a of the Biospecimen Collection (BIC1) form and the oral swab Chlamydia result is recorded in item 1a of the Biospecimen Results (BLR1) Form for Baseline (T1).

Variable: CH_ORAL_T1_1

Label: Assessment of Chlamydia using an Oral Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC10a = 1 then CH_ORAL_T1_1 = [BLR1] BLR1a
Else if [BIC1] BIC10a=1 and [BLR1] BLR1a=. then CH_ORAL_T1_1 = .U
Else if [BIC1] BIC10a=0 then CH_ORAL_T1_1 = .N
Else if [BIC1] BIC10a=9 then CH_ORAL_T1_1 = .R
Else if [BIC1] BIC10a=. then CH_ORAL_T1_1 = .

2.3.1.2. Chlamydia Result based on Anal Sample at T1

Description: The anal sample collection status is recorded in item 11a of the BIC1 form and the anal swab Chlamydia result is recorded in item 2a of the BLR1 Form for Baseline (T1).

Variable: CH_ANAL_T1_1

Label: Assessment of Chlamydia using an Anal Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC11a = 1 then CH_ANAL_T1_1 = [BLR1] BLR2a
Else if [BIC1] BIC11a=1 and [BLR1] BLR2a=. then CH_ANAL_T1_1 = .U
Else if [BIC1] BIC11a=0 then ANAL_CH_T1_1 = .N
Else if [BIC1] BIC11a=9 then ANAL_CH_T1_1 = .R
Else if [BIC1] BIC11a=. then ANAL_CH_T1_1 = .

2.3.1.3. Chlamydia Result based on Urine Sample at T1

Description: The urine sample collection status is recorded in item 12a of BIC1 form and the urine Chlamydia result is recorded in item 3a of BLR1 Form for Baseline (T1).

Variable: CH_URINE_T1_1

Label: Assessment of Chlamydia using a Urine Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC12a = 1 then CH_URINE_T1_1 = [BLR1] BLR3a
Else if [BIC1] BIC12a=1 and [BLR1] BLR3a=. then CH_URINE_T1_1 = .U
Else if [BIC1] BIC12a=0 then CH_URINE_T1_1 = .N

Else if [BIC1] BIC12a=9 then CH_URINE_T1_1 = .R
Else if [BIC1] BIC12a=. then CH_URINE_T1_1 = .

2.3.2. Chlamydia Result at Month 8 Follow-Up (T3)

2.3.2.1. Chlamydia Result based on Oral Sample at T3

Description: The oral sample collection status is recorded in item 10a of the Biospecimen Collection (BIC2) form and the oral swab Chlamydia result is recorded in item 1a of the Biospecimen Results (BLR2) Form for 8-Month Follow-up (T3).

Variable: CH_ORAL_T3_1

Label: Assessment of Chlamydia using an Oral Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC10a = 1 then CH_ORAL_T3_1 = [BLR2] BLR1a
Else if [BIC2] BIC10a=1 and [BLR2] BLR1a=. then CH_ORAL_T3_1 = .U
Else if [BIC2] BIC10a=0 then CH_ORAL_T3_1 = .N
Else if [BIC2] BIC10a=9 then CH_ORAL_T3_1 = .R
Else if [BIC2] BIC10a=. then CH_ORAL_T3_1 = .

2.3.2.2. Chlamydia Result based on Anal Sample at T3

Description: The anal sample collection status is recorded in item 11a of the BIC2 form and the anal swab Chlamydia result is recorded in item 2a of the BLR2 Form for the Month 8 follow-up (T3).

Variable: CH_ANAL_T3_1

Label: Assessment of Chlamydia using an Anal Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC11a = 1 then CH_ANAL_T3_1 = [BLR2] BLR2a
Else if [BIC2] BIC11a=1 and [BLR2] BLR2a=. then CH_ANAL_T3_1 = .U
Else if [BIC2] BIC11a=0 then CH_ANAL_T3_1 = .N
Else if [BIC2] BIC11a=9 then CH_ANAL_T3_1 = .R
Else if [BIC2] BIC11a=. then CH_ANAL_T3_1 = .

2.3.2.3. Chlamydia Result based on Urine Sample at T3

Description: The urine sample collection status is recorded in item 12a of BIC2 form and the urine Chlamydia result is recorded in item 3a of BLR2 Form for Month 8 follow-up (T3).

Variable: CH_URINE_T3_1

Label: Assessment of Chlamydia using a Urine Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC12a = 1 then CH_URINE_T3_1 = [BLR2] BLR3a
Else if [BIC2] BIC12a=1 and [BLR2] BLR3a=. then CH_URINE_T3_1 = .U
Else if [BIC2] BIC12a=0 then CH_URINE_T3_1 = .N
Else if [BIC2] BIC12a=9 then CH_URINE_T3_1 = .R
Else if [BIC2] BIC12a=. then CH_URINE_T3_1 = .

2.3.3. Change in Chlamydia Result from Baseline to Month 8 Follow-Up (T1T3)

2.3.3.1. Change in Chlamydia Result based on Oral Samples at T1T3

Description: Change in Chlamydia oral sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: CH_ORAL_T1T3_1

Label: Change in Chlamydia Oral Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Anal Result, -1=Positive to Negative

Algorithm: CH_ORAL_T1T3_1 = CH_ORAL_T3_1 – CH_ORAL_T1_1

If measurement at either time point is missing, then CH_ORAL_T1T3_1 = missing.

2.3.3.2. Change in Chlamydia Result based on Anal Samples at T1T3

Description: Change in Chlamydia anal sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: CH_ANAL_T1T3_1

Label: Change in Chlamydia Anal Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Anal Result, -1=Positive to Negative

Algorithm: CH_ANAL_T1T3_1 = CH_ANAL_T3_1 – CH_ANAL_T1_1

If measurement at either time point is missing, then CH_ANAL_T1T3_1 = missing.

2.3.3.3. Change in Chlamydia Result based on Urine Samples at T1T3

Description: Change in Chlamydia urine sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: CH_URINE_T1T3_1

Label: Change in Chlamydia Urine Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Anal Result, -1=Positive to Negative

Algorithm: CH_URINE_T1T3_1 = CH_URINE_T3_1 – CH_URINE_T1_1

If measurement at either time point is missing, then CH_URINE_T1T3_1 = missing.

2.4. GONORRHEA INFECTIONS:

Gonorrhea will be assessed at T1 (Baseline) and T3 (8-Month follow-up) using urine, anal, and oral sample tests.

2.4.1. Gonorrhea Result at Baseline (T1)

2.4.1.1. Gonorrhea Result based on Oral Sample at T1

Description: The oral sample collection status is recorded in item 10a of the BIC1 form and the oral swab Gonorrhea result is recorded in item 1b of the BLR1 Form for Baseline (T1).

Variable: GN_ORAL_T1_1

Label: Assessment of Gonorrhea using an Oral Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC10a = 1 then GN_ORAL_T1_1 = [BLR1] BLR1b
Else if [BIC1] BIC10a=1 and [BLR1] BLR1b=. then GN_ORAL_T1_1 = .U
Else if [BIC1] BIC10a=0 then GN_ORAL_T1_1 = .N
Else if [BIC1] BIC10a=9 then GN_ORAL_T1_1 = .R
Else if [BIC1] BIC10a=. then GN_ORAL_T1_1 = .

2.4.1.2. Gonorrhea Result based on Anal Sample at T1

Description: The anal sample collection status is recorded in item 11a of the BIC1 form and the anal swab Gonorrhea result is recorded in item 2b of the BLR1 Form for Baseline (T1).

Variable: GN_ANAL_T1_1

Label: Assessment of Gonorrhea using an Anal Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC11a = 1 then GN_ANAL_T1_1 = [BLR1] BLR2b
Else if [BIC1] BIC11a=1 and [BLR1] BLR2b=. then GN_ANAL_T1_1 = .U
Else if [BIC1] BIC11a=0 then GN_ANAL_T1_1 = .N
Else if [BIC1] BIC11a=9 then GN_ANAL_T1_1 = .R
Else if [BIC1] BIC11a=. then GN_ANAL_T1_1 = .

2.4.1.3. Gonorrhea Result based on Urine Sample at T1

Description: The urine sample collection status is recorded in item 12a of BIC1 form and the urine Gonorrhea result is recorded in item 3b of BLR1 Form for Baseline (T1).

Variable: GN_URINE_T1_1

Label: Assessment of Gonorrhea using a Urine Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC12a = 1 then GN_URINE_T1_1 = [BLR1] BLR3b
Else if [BIC1] BIC12a=1 and [BLR1] BLR3b=. then GN_URINE_T1_1 = .U
Else if [BIC1] BIC12a=0 then GN_URINE_T1_1 = .N
Else if [BIC1] BIC12a=9 then GN_URINE_T1_1 = .R
Else if [BIC1] BIC12a=. then GN_URINE_T1_1 = .

2.4.2. Gonorrhea Result at Month 8 Follow-Up (T3)

2.4.2.1. Gonorrhea Result based on Oral Sample at T3

Description: The oral sample collection status is recorded in item 10a of the BIC2 form and the oral swab Gonorrhea result is recorded in item 1b of the BLR2 Form for 8-Month follow-up (T3).

Variable: GN_ORAL_T3_1

Label: Assessment of Gonorrhea using an Oral Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC10a = 1 then GN_ORAL_T3_1 = [BLR2] BLR1b
Else if [BIC2] BIC10a=1 and [BLR2] BLR1b=. then GN_ORAL_T3_1 = .U
Else if [BIC2] BIC10a=0 then GN_ORAL_T3_1 = .N
Else if [BIC2] BIC10a=9 then GN_ORAL_T3_1 = .R
Else if [BIC2] BIC10a=. then GN_ORAL_T3_1 = .

2.4.2.2. Gonorrhea Result based on Anal Sample at T3

Description: The anal sample collection status is recorded in item 11a of the BIC2 form and the anal swab Gonorrhea result is recorded in item 2b of the BLR2 Form for the Month 8 follow-up (T3).

Variable: GN_ANAL_T3_1

Label: Assessment of Gonorrhea using an Anal Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC11a = 1 then GN_ANAL_T3_1 = [BLR2] BLR2b
Else if [BIC2] BIC11a=1 and [BLR2] BLR2b=. then GN_ANAL_T3_1 = .U
Else if [BIC2] BIC11a=0 then GN_ANAL_T3_1 = .N
Else if [BIC2] BIC11a=9 then GN_ANAL_T3_1 = .R
Else if [BIC2] BIC11a=. then GN_ANAL_T3_1 = .

2.4.2.3. Gonorrhea Result based on Urine Sample at T3

Description: The urine sample collection status is recorded in item 12a of BIC2 form and the urine Gonorrhea result is recorded in item 3b of BLR2 Form for Month 8 follow-up (T3).

Variable: GN_URINE_T3_1

Label: Assessment of Gonorrhea using a Urine Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC12a = 1 then GN_URINE_T3_1 = [BLR2] BLR3b
Else if [BIC2] BIC12a=1 and [BLR2] BLR3b=. then GN_URINE_T3_1 = .U
Else if [BIC2] BIC12a=0 then GN_URINE_T3_1 = .N
Else if [BIC2] BIC12a=9 then GN_URINE_T3_1 = .R

Else if [BIC2] BIC12a=. then GN_URINE_T3_1 = .

2.4.3. Change in Gonorrhea Result from Baseline to Month 8 Follow-Up (T1T3)

2.4.3.1. Change in Gonorrhea Result based on Oral Samples at T1T3

Description: Change in Gonorrhea oral sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: GN_ORAL_T1T3_1

Label: Change in Gonorrhea Oral Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Oral Result, -1=Positive to Negative

Algorithm: GN_ORAL_T1T3_1 = GN_ORAL_T3_1 – GN_ORAL_T1_1

If measurement at either time point is missing, then GN_ORAL_T1T3_1 = missing.

2.4.3.2. Change in Gonorrhea Result based on Anal Samples at T1T3

Description: Change in Gonorrhea anal sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: GN_ANAL_T1T3_1

Label: Change in Gonorrhea Anal Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Anal Result, -1=Positive to Negative

Algorithm: GN_ANAL_T1T3_1 = GN_ANAL_T3_1 – GN_ANAL_T1_1

If measurement at either time point is missing, then GN_ANAL_T1T3_1 = missing.

2.4.3.3. Change in Gonorrhea Result based on Urine Samples at T1T3

Description: Change in Gonorrhea urine sample result of a participant from Baseline to Month 8 follow-up (T1 to T3)

Variable: GN_URINE_T1T3_1

Label: Change in Gonorrhea Urine Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea urine result, -1=Positive to Negative

Algorithm: GN_URINE_T1T3_1 = GN_URINE_T3_1 – GN_URINE_T1_1

If measurement at either time point is missing, then GN_URINE_T1T3_1 = missing.

2.5. REACTIVE HIV TEST

Description: Testing for HIV is conducted at Baseline (T1) and Month 8 follow-up (T3) and indicates whether or not the test result was reactive or non-reactive. The reactive HIV testing result for T3 is recorded in item 1a of the BIC2 form.

Variable: HIVREAC_T3_1

Label: Reactive HIV Test Result at T3.

Type: Numeric; Format: 0=Non-Reactive, 1=Reactive, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC1=1 then HIVREAC_T3_1= [BIC2] BIC1a
Else if [BIC2] BIC1=1 and [BIC2] BIC1a=. then HIVREAC_T3_1=.U
Else if [BIC2] BIC1=0 then HIVREAC_T3_1_1 = .N
Else if [BIC2] BIC1=9 and [BIC2] BIC1a=9 then HIVREAC_T3_1=.R
Else if [BIC2] BIC1=. and [BIC2] BIC1a=. then HIVREAC_T3_1=.

Statistical Analysis Plan: Work2Prevent – Phase 3

PROTOCOL:	ATN 151: Work2Prevent: Employment as HIV prevention for young men who have sex with men (YMSM) and young transgender women (YTW)
PROTOCOL DATE:	May 23, 2017 Revised August 5, 2019
PROTOCOL VERSION:	5.1
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SAP PREPARED BY:	ATN Coordinating Center Collaborative Studies Coordinating Center Department of Biostatistics The University of North Carolina at Chapel Hill 123 W. Franklin Street, Suite 450, CB# 8030 Chapel Hill, NC 27599-8030
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Brandon Hill	Principal Investigator		
Darnell Motley	Site Investigator		

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ATN	Adolescent Medicine Trials Network for HIV/AIDS Interventions
CAI	Condomless Anal Intercourse
CC	ATN Coordinating Center
CSCC	Collaborative Studies Coordinating Center
HIV	Human Immunodeficiency Virus
HQ	Handbook Quality
IQ	Information Quality
ISSM	Information Systems Success Model
JSS	Job-Seeking Self-Efficacy
MSM	Men who have Sex with Men
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
PCA	Protean Career Attitudes
PU	Perceived Usefulness
SDA	Self-Directed Attitudes
STI	Sexually Transmitted Infection
T1	Baseline Visit
T2	Post-Intervention Visit at 0-2 weeks post-intervention
T3	Follow-up Visit at 3-months (±2 weeks) post-intervention
VDA	Values-Driven Attitudes
W2P	Work2Prevent
YMSM	Young Men who have Sex with Men
YTW	Young Transgender Women

1. INTRODUCTION

Work2Prevent (W2P) is a study designed to adapt, tailor, and pilot-test a novel social and structural-level HIV intervention for Young Men who have Sex with Men (YMSM) and Young Transgender Women (YTW) of color aimed at increasing economic stability (i.e., employment) through youth empowerment, increased self-efficacy, and decreased HIV risk behaviors (i.e., sex work) associated with social and economic marginalization. This document provides details of the planned statistical analysis for Phase 3 of intervention.

1.1. Objectives and Research Hypotheses

The primary objective of Phase 3 is to pilot-test a intervention among up to 40 at-risk YMSM and YTW of color to evaluate feasibility and acceptability. Investigators hypothesize the intervention will increase job self-efficacy and readiness, as well as decrease HIV risk behaviors and STI and HIV infections.

2. STUDY METHODS

2.1. Study Design

W2P is a single-arm longitudinal pre and post study of a social and structural-level employment intervention to evaluate feasibility, acceptability, and satisfaction of the intervention program, and preliminary efficacy for study outcomes assessed at Baseline (T1), Post-Intervention (T2, 0 to 2 weeks post workshop completion), and 3-Month Follow-up (±2 weeks) (T3). The study employment intervention is comprised of four structured workshops presented over a 2-day period.

The study aims to enroll up to 40 at-risk YMSM and YTW of color over a 6-month period. The intervention workshops will be completed within 4 weeks of enrollment. Each participant will then be assessed 3-months (±2 weeks) post-intervention.

Study outcomes include: (1) job self-efficacy and readiness; (2) HIV risk behaviors; (3) employment; and (4) STI and HIV infections.

2.2. Study Population

All intervention study participants are Black, African American, Hispanic, or Latinx males, including transgender women (those assigned male at birth), ages 16-24, who identify as either an (1) MSM or gay or bisexual man or as a (2) transgender woman or transsexual male-to-female or transwoman.

Participant Inclusion Criteria:

1. Being male or assigned male at birth (YTW)
2. Identifying as YMSM, gay bisexual man, transgender woman, or transwoman
3. Identifying as African American, Black, Hispanic, or Latinx
4. 16-24 years old
5. English-speaking (primary)
6. Currently unemployed but seeking employment, or employed only part-time (average of 35 hours or less per week)
7. Able to attend a 4-session employment program over 2 days
8. Did not participate in Phase 2 pilot

Participant Exclusion Criteria:

1. Individuals identifying as non-Hispanic White
2. Individuals not assigned male at birth

2.3. Sample Size Information

This study aims to enroll up to 40 participants. Given the exploratory nature of this study and limited access to this population, a power calculation was not performed. A repeated measures design was chosen to reduce the variability in the estimate of the treatment effect, at the expense of having a comparison group. In addition, practice or fatigue effects from repetition may affect certain outcomes (e.g. protean career attitudes scale and subscales). This trade-off was appropriate given the exploratory nature of a pilot study and the limited access to the study population.

3. ANALYSIS POPULATIONS

Only participants who are enrolled at Baseline (complete the T1 survey) will be included in the primary and secondary analyses. Screen-failures will not be included in these analyses.

3.1. Intent-to-Treat Population

All participants who completed T3 will be included in intent-to-treat analyses involving variables measuring changes from T1 to T3 (see sections 4.1.3-4.1.4 and 4.2.1-4.2.5 below). All participants who completed at least one workshop will be included in intent-to-treat analyses involving workshop evaluation and workshop completion variables (see sections 4.1.1, 4.1.2 below). This population will form the basis for both the primary and secondary analyses of the efficacy and safety endpoints.

3.2. Per Protocol Population

Youth who attend at least two of the four planned intervention workshops and complete T3 will comprise the per protocol population. This population will form the basis for both the primary and secondary analyses of the efficacy and safety endpoints.

4. STUDY ASSESSMENTS

Study Assessments	Pre-Screening	Baseline (T1)	Post-Intervention (T2)	3-Month Follow-Up (T3)
Screener Survey (SCR)	X			
Eligibility Form (ELG)		X		
Baseline Survey (BSL)		X		
Biospecimen Collection Form (BIC)		X		X
Biospecimen Lab Results Form (BLR)		X		X
Workshop Tracking (WTI)			X	
Workshop Evaluation (EVL)			X	
Exit Visit Survey (EXQ)				X

4.1. Primary Outcomes

4.1.1. Information Systems Success Model Score (T2)

The Information Systems Success Model (ISSM) will be used to assess for intervention acceptability and satisfaction. The 21-item scale measures four sub-domains: information quality, handbook quality, perceived usefulness, and overall satisfaction. Every item is scored on a 1 to 5 scale, with 1 being “Strongly Disagree” and 5 being “Strongly Agree”. Responses are averaged within each sub-domain to produce four sub-domain scores. The four sub-domain scores are then averaged to produce an overall ISSM score (range: 1 to 5; higher scores indicate higher acceptability/satisfaction). This scale has been adapted from Horvath et al.[1]

4.1.2. Workshop Completion (T2)

Workshop completion will be used to assess for intervention feasibility. The outcome of intervention completion is defined as having attended at least two of the four workshop sessions and is measured by tracking participant attendance. Workshop completion may also be defined as the number of workshop sessions attended for use in exploratory analyses.

4.1.3. Change in Job-Seeking Self-Efficacy Scale Score (T1 to T3)

Job seeking self-efficacy is defined as one’s perceived ability and confidence to perform job search and application activities. The 12-item Job Seeking Self-Efficacy (JSS) scale by Barlow, Wright, & Cullen[2] uses response values on a 1 to 10 score, with 1 being “Not At All Confident”

and 10 being “Very Confident”. Reponses are averaged to yield a total score, with higher scores indicating higher self-efficacy. Change in JSS will be calculated by subtracting the JSS score at baseline (T1) from the JSS score at the 3-month follow-up (T3) (range: -9 to +9; negative change indicates decreased self-efficacy, while positive change indicates increased self-efficacy).

4.1.4. Change in Protean Career Attitudes Scale Score (T1 to T3)

Protean career attitudes (PCAs) are defined as having self-direction in the pursuit of success in one’s work. PCAs have previously been found to be associated with positive career satisfaction and self-perceived success.[3] The validated 7-item scale by Porter, Woo, & Tak[4] measures two sub-domains: self-directed attitudes and value-driven attitudes. Every item is scored on a 1 to 5 scale, with 1 being “Strongly Disagree” and 5 being “Strongly Agree”. Responses are averaged within each sub-domain to produce two sub-domain scores, which are then averaged to produce an overall PCA score. Change in PCA score will be calculated by subtracting the score at baseline (T1) from the score at the 3-month follow-up (T3) (range: -4 to +4; negative change indicates decreased PCAs, while positive change indicates increased PCAs).

4.2. Secondary Outcomes

4.2.1. Change in Self-Reported Hours Worked Per Week (T1 to T3)

Hours worked per week will be self-reported at baseline and at the 3-month follow-up visit as any value between 0 and 99. Change in hours worked per week will be calculated by subtracting the baseline (T1) value from the 3-month follow-up (T3) value. Negative change indicates fewer hours worked per week, while positive change indicates more hours worked per week.

4.2.2. Change in Self-Reported Sexual Risk Behaviors (T1 to T3)

Sexual risk behaviors will be measured using six yes or no (1 or 0) items assessing for engagement in the following behaviors during the 3 months prior to baseline (T1) and 3-month follow-up (T3) assessments:

1. Condomless anal intercourse (CAI) with male partner of unknown HIV status
2. Anal intercourse with ≥3 males
3. Sex with male partner with a Sexually Transmitted Infection (STI)
4. CAI with HIV+ male partner
5. Anal intercourse with condom failure
6. Transactional sex work involvement

Responses will be averaged at each assessment. Change in sexual risk behaviors will be calculated by subtracting the average at baseline from the average at the 3-month follow-up (range: -1 to +1; negative change indicates fewer sexual risk behaviors, while positive change indicates more sexual risk behaviors).

4.2.3. Change in Chlamydia Test Result (T1 to T3)

Chlamydia infections will be assessed at baseline and 3-month follow up using oral, anal, and urine samples. Each of the three tests yields a positive (1) or negative (0) result. Change in test result will be calculated by subtracting the baseline result from the 3-month follow-up result. Oral, anal, and urine tests will be treated as separate outcomes.

4.2.4. Change in Gonorrhea Test Result (T1 to T3)

Gonorrhea infections will be assessed at baseline and 3-month follow up using oral, anal, and urine samples. Each of the three tests yields a positive (1) or negative (0) result. Change in test result will be calculated by subtracting the baseline result from the 3-month follow-up result. Oral, anal, and urine tests will be treated as separate outcomes.

4.2.5. Reactive HIV Test (T3)

Testing for HIV will be assessed at baseline and 3-month follow up. The test yields a reactive (1) or non-reactive (0) result. The outcome for reactive HIV test will use the T3 test result.

5. STATISTICAL ANALYSIS

5.1. General Considerations

The analytic plan is designed to determine preliminary efficacy of the intervention by comparing pre and post assessments of employment and sexual risk behaviors. Descriptive statistics will be used to analyze the proportions and central tendencies for participant sociodemographic covariates collected in the surveys. We will first generate frequencies, means, and other measures of central tendency as appropriate to describe our sample and outcomes at each of the three time points (baseline, post-intervention, and 3-month follow-up).

Changes in primary and secondary outcomes between baseline and 3-month follow-up will be assessed using paired t-tests for continuous variables and McNemar's test for matched categorical variables. We will use standard diagnostic tools to assess the appropriateness of the normality assumption (e.g., QQ-plots) and, if approximate normality of the residuals is not tenable, a non-parametric test for continuous paired data, i.e., Wilcoxon sign rank test will be used. All hypothesis testing will be done at an alpha-level of 0.1, given the exploratory nature of the study.

5.2. Missing Data

Missing responses to survey questions will be excluded and non-missing data will be used to compute the primary and secondary outcomes. If all components for an outcome are missing, then the outcome will be considered missing. For those outcomes with unique missing data rules, the handling of missing data for each individual outcome are described in the appendix.

Missing data patterns will be explored prior to the analysis of the primary and secondary outcomes.

5.3. Subject Disposition Analyses

Number of participants pre-screened, screened, eligible, discontinued, and included in the per protocol analysis population will be reported. In addition, the number of participants completing each visit (T1, T2 and T3) and the reasons for patient discontinuation will be tabulated.

5.4. Analysis of Primary Outcomes

Primary outcomes for analyses include Information Systems Success Model score, workshop completion, change in Job-Seeking Self Efficacy Scale score, Protean Career Attitudes Scale score, change in Self-Directed Attitudes Scale score, and change in Values-Driven Attitudes Scale score. Details about these outcomes are described in Section 4.1.

Univariate analyses will be performed as described in Section 5.1. To the extent that data allows, multivariable analyses will adjust for sociodemographic characteristics, workshop attendance, baseline employment status, and study completeness. Analytical models will include linear regression or generalized linear models for continuous outcomes and logistic regression for binary and categorical outcomes.

5.5. Analysis of Secondary Outcomes

Secondary outcomes for analyses include change in self-reported hours worked per week, change in self-reported sexual risk behavior, change in chlamydia test results, change in gonorrhea test results, and reactive HIV test result. Details about these outcomes are described in Section 4.2.

Univariate analyses will be performed as described in Section 5.1. Multivariable analyses will adjust for sociodemographic characteristics, workshop attendance, baseline employment status, and study completeness. Analytical models will include linear regression or generalized linear models for continuous outcomes and logistic regression for binary and categorical outcomes.

5.6. Analysis of Safety Events

Safety events will be recorded for participants as needed throughout the study. The number of participants experiencing each safety event will be summarized by severity grade, relationship to study, and action taken. All safety events will be provided in the safety events data listing. Withdrawals due to safety events will also be reported.

REFERENCES

1. Horvath KJ, Oakes MJ, Rosser SBR, Danilenko G, Vezina H, Amico RK, Williams ML, Simoni J. *Feasibility, Acceptability and Preliminary Efficacy of an Online Peer-to-Peer Social Support ART Adherence Intervention.* AIDS Behav., 2013; 17:2031-2044.

2. Barlow J, Wright C, Cullen L. *A job-seeking self-efficacy scale for people with physical disabilities: preliminary development and psychometric testing.* Br J Guid Counc., 2002; 30:1, 37-53.

3. Volmer J, Spurk D. *Protean and boundaryless career attitudes: relationships with subjective and objective career success.* J Labor Mark Res., 2011; 43:207-218.

4. Porter C, Woo SE, Tak J. *Developing and Validating Short Form Protean and Boundaryless Career Attitudes Scales.* J Career Assess., 2016; 24(1):162-181.

APPENDIX

1. PRIMARY OUTCOMES

1.1. INFORMATION SYSTEMS SUCCESS MODEL (ISSM) SCALE

The Information Systems Success Model (ISSM) scale has been adapted from Horvath et al.[1] to assess intervention acceptability and satisfaction. The scale evaluates four sub-domains: information quality, system quality, perceived usefulness, and overall satisfaction. For each of the calculated scores, higher values indicate better participant-assessed quality.

1.1.1. ISSM Subscale 1: Information Quality (IQ) Score

Description: Information Quality is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate ease of comprehension, credibility, clarity, and accuracy of the information provided through the intervention using responses to items 7a through 7e and 8a in the Evaluation (EVL) Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: IQ_T2_1

Label: Information Quality Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: IQ_T2_1 = MEAN (EVL7a, EVL7b, EVL7c, EVL7d, EVL7e, EVL8a)

If all responses are missing, then then IQ_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.2. ISSM Subscale 2: Handbook Quality (HQ) Score

Description: Handbook Quality is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate user friendliness and appeal of the workshop handbook provided through the intervention using responses to items 8b through 8e, 9a, and 9b in the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: HQ_T2_1

Label: Handbook Quality Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: HQ_T2_1 = MEAN (EVL8b, EVL8c, EVL8d, EVL8e, EVL9a, EVL9b)

If all responses are missing, then HQ_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.3. ISSM Subscale 3: Perceived Usefulness (PU) Score

Description: Perceived Usefulness is a 6-item sub-scale measured at time point T2 (post-intervention) to evaluate the usefulness of the intervention to help the participant to achieve their career-related goals using responses to items 6c, 9c through 9e, 10a, and 10b in the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: PU_T2_1

Label: Perceived Usefulness Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: PU_T2_1 = MEAN (EVL6c, EVL9c, EVL9d, EVL9e, EVL10a, EVL10b)

If all responses are missing, then PU_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.4. ISSM Subscale 4: Overall Score

Description: The Overall Score is a 3-item sub-scale measured at time point T2 (post-intervention) to evaluate the overall satisfaction with the workshops using responses to items 10c through 10e from the EVL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: OVERALL_T2_1

Label: Overall Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: OVERALL_T2_1 = MEAN (EVL10c, (6 - EVL10d), EVL10e)

If all responses are missing, then OVERALL _T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.1.5. Information Systems Success Model (ISSM) Score

Description: The ISSM Score is obtained by adding the four subscale scores defined above: IQ Score, HQ Score, PU Score, and Overall Score.

Variable: ISSM_T2_1

Label: Information Systems Success Model Score at T2

Type: Numeric; Range = 1 to 5

Algorithm: ISSM_T2_1 = MEAN (IQ_T2_1, HQ_T2_1, PU_T2_1, OVERALL_T2_1).

If all responses are missing, then ISSM_T2_1=Missing. Otherwise, consider mean of non-missing responses.

1.2. WORKSHOP COMPLETION

Workshop completion will be used in the assessment of intervention feasibility. The primary outcome for workshop completion will be measured using a binary outcome of Complete vs. Not Complete (1.2.2), but the number of completed workshops (1.2.1) is also defined to assess potential dose response of the workshop intervention on other outcomes.

1.2.1. Number of Workshops Attended

Description: The participants' workshop attendance is recorded in items 3a, 3c, 4a, 4c, 5a, 5c, 6a, and 6c of the Workshop Tracking Information (WTI) form.

Variable: WSATTEND_T2_1

Label: Number of Workshops Attended at T2

Type: Numeric; Range = 0 to 4

Algorithm: WSATTEND_T2_1 = SUM (WTI3a, WTI3c, WTI4a, WTI4c, WTI5a, WTI5c, WTI6a, WTI6c)

If all responses are missing, then WSATTEND_T2_1=Missing. Otherwise, sum non-missing responses. Note: WTI#c can only have a response if WTI#a=0.

1.2.2. Workshop Completion

Description: Workshop completion is defined as having attended at least two of the four workshop sessions (50% completion).

Variable: WSCOMP_T2_1

Label: Workshop Completion at T2

Type: Numeric; Format: 0=Not Complete, 1=Complete, .=Missing

Algorithm: If WSATTEND_T2_1 >= 2 then WSCOMP_T2_1 = 1
Else if WSATTEND_T2_1 in (0, 1) then WSCOMP_T2_1=0
Else WSCOMP_T2_1 = .

1.3. JOB SEEKING SELF-EFFICACY SCALE SCORE

Job seeking self-efficacy is defined as one's perceived ability and confidence to perform job search and application activities. Higher values indicate higher self-efficacy. This scale is measured at Baseline (T1) and the Month 3 Follow-up (T3).

1.3.1. Job Seeking Self-Efficacy Score at Baseline (T1)

Description: Job Seeking Self-Efficacy score at time point T1 (Baseline) is based on 12 items (52a through 52f and 53a through 53f) from the BSL Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T1_1

Label: Job-Seeking Self Efficacy Score at T1

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T1_1 = MEAN(BSL52a, BSL52b, BSL52c, BSL52d, BSL52e, BSL52f, BSL53a, BSL53b, BSL53c, BSL53d, BSL53e, BSL53f)

If all responses are missing, then JOBSEEK_T1_1=Missing. Otherwise, calculate the mean ofthe non-missing responses.

1.3.2. Job Seeking Self-Efficacy Score at Post-Intervention (T2)

Description: Job Seeking Self-Efficacy score at time point T2 (Post-Intervention) is based on 12 items (13a through 13f and 14a through 14f) from the EVL Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T2_1

Label: Job-Seeking Self Efficacy Score at T2

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T2_1 = MEAN (EVL13a, EVL13b, EVL13c, EVL13d, EVL13e, EVL13f, EVL14a, EVL14b, EVL14c, EVL14d, EVL14e, EVL14f)

If all responses are missing, then JOBSEEK_T2_1=Missing. Otherwise, calculate the mean ofthe non-missing responses.

1.3.3. Job Seeking Self-Efficacy Score at Month 3 Follow-Up (T3)

Description: Job Seeking Self-Efficacy score at time point T3 (Month 3 follow-up) is based on 12 items (52a through 52f and 53a through 53f) from the EXQ Questionnaire. Responses are scored on the scale 1/Not at all confident = 1 point to 10/Very Confident = 10 points.

Variable: JOBSEEK_T3_1

Label: Job-Seeking Self Efficacy Score at T3

Type: Numeric; Range = 1 to 10

Algorithm: JOBSEEK_T3_1 = MEAN (EXQ52a, EXQ52b, EXQ52c, EXQ52d, EXQ52e, EXQ52f, EXQ53a, EXQ53b, EXQ53c, EXQ53d, EXQ53e, EXQ53f)

If all responses are missing, then JOBSEEK_T3_1=Missing. Otherwise, calculate the mean ofnon-missing responses

1.3.4. Change in Job Seeking Self-Efficacy Score from Baseline to Month 3 Follow-Up (T1T3)

Description: Difference between Job Seeking Self-Efficacy score at the Month 3 follow-up (T3) and the score at Baseline (T1). If the Job Seeking Self-Efficacy score is missing at T3, then the score from T2 is used to compute the change in score from T1.

Variable: JOBSEEK_T1T3_1

Label: Change in Job-Seeking Self Efficacy Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -9 to 9

Algorithm: If JOBSEEK_T3_1 not . then JOBSEEK_T1T3_1=JOBSEEK_T3_1 – JOBSEEK_T1_1
Else if JOBSEEK_T3_1=. then JOBSEEK_T1T3_1=JOBSEEK_T2_1 – JOBSEEK_T1_1

If JOBSEEK_T1_1 is missing, then JOBSEEK_T1T3_1=Missing. If JOBSEEK_T2_1 and JOBSEEK_T3_1 are missing, then JOBSEEK_T1T3_1=Missing.

1.4. PROTEAN CAREER ATTITUDES SCALE (PCA) SCORE:

Protean career attitudes are defined as having self-direction in the pursuit of success in one's work. The scale (and the two sub scales) were measured at Baseline (T1) and the Month 3 follow-up (T3). Higher values indicate better attitudes.

1.4.1. PCA Subscale 1: Self-Directed Attitudes (SDA) Scale Score

1.4.1.1. Self-Directed Attitudes Score at Baseline (T1)

Description: Self-directed Attitudes Scale Score at time point T1 (Baseline) is based on four items (75b, 75c, 75d, and 76a) from the BSL Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: SDA_T1_1

Label: Self-Directed Attitudes Scale Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: SDA_T1_1 = MEAN (BSL75b, BSL75c, BSL 75d, BSL76a)

If all responses are missing, then SDA_T1_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.4.1.2. Self-Directed Attitudes Score at Month 3 Follow-Up (T3)

Description: Self-directed Attitudes Scale Score at time point T3 (Month 3 follow-up) is based on four items (75b, 75c, 75d, and 76a) from the EXQ Questionnaire. Responses are recorded as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: SDA_T3_1

Label: Self-Directed Attitudes Scale Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: SDA_T3_1 = MEAN (EXQ75b, EXQ75c, EXQ75d, EXQ76a)

If all responses are missing, then SDA_T3_1=Missing. Otherwise, calculate the mean of non-missing responses.

1.4.1.3. Change in Self-Directed Attitudes Score from Baseline to Month 3 Follow-Up (T1T3)

Description: Difference between Self-Directed Attitudes score at time point T3 (Month 3 follow-up) and time point T1 (Baseline)

Variable: SDA_T1T3_1

Label: Change in Self-Directed Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: SDA_T1T3_1 = SDA_T3_1 – SDA_T1_1

If SDA score at either time point is missing, then SDA_T1T3_1=Missing.

1.4.2. PCA Subscale 2: Values-Driven Attitudes Scale Score

1.4.2.1. Values-Driven Attitudes (VDA) Score at Baseline (T1)

Description: Values driven Attitudes Scale Score at time point T1 (Baseline) is based on 3 items (76b, 76c, and 76d) from the BSL Questionnaire. Response are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points.

Variable: VDA_T1_1

Label: Values-Driven Attitudes Scale Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: VDA_T1_1 = MEAN (BSL76b, BSL76c, BSL76d)

If all responses are missing, then VDA_T1_1=Missing. Otherwise, calculate the mean ofnon-missing responses.

1.4.2.2. Values-Driven Attitudes (VDA) Score at Month 3 Follow-Up (T3)

Description: Values driven Attitudes Scale Score at time point T3 (Month 3 follow-up) is based on 3 items (76b, 76c, and 76d) from the EXQ Questionnaire. Responses are scored as 1/Strongly Disagree = 1 point, 2/Disagree = 2 points, 3/Neither Disagree nor Agree = 3 points, 4/Agree = 4 points, and 5/Strongly Agree = 5 points

Variable: VDA_T3_1

Label: Values-Driven Attitudes Scale Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: VDA_T3_1 = MEAN (EXQ76b, EXQ76c, EXQ76d)

If all responses are missing, then VDA_T3_1=Missing. Otherwise, calculate the mean ofnon-missing responses.

1.4.2.3. Change in Values-Driven Attitudes (VDA) Score from Baseline to Month 3 Follow-Up (T1T3)

Description: Difference between Values-Driven Attitudes Score at time point T3 (Month 3 follow-up) from time point T1 (Baseline)

Variable: VDA_T1T3_1

Label: Change in Values Driven Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: VDA_T1T3_1 = VDA_T3_1 – VDA_T1_1

If VDA score at either time point is missing, then VDA_T1T3_1=Missing.

1.4.3. Scale: Protean Career Attitudes (PCA) Scale

1.4.3.1. Protean Career Attitudes (PCA) Score at Baseline (T1)

Description: The Protean Career Attitudes Score at T1 is obtained by adding the two subscale scores defined above: SDA Score at T1 and VDA Score at T1.

Variable: PCA_T1_1

Label: Protean Career Attitudes Score at T1

Type: Numeric; Range = 1 to 5

Algorithm: PCA_T1_1 = MEAN (SDA_T1_1, VDA_T1_1)

If either SDA or VDA score is missing, then PCA_T1_1=Missing.

1.4.3.2. Protean Career Attitudes (PCA) Score at Month 3 Follow-Up (T3)

Description: The Protean Career Attitudes Score at T3 is obtained by adding the two subscale scores defined above: SDA Score at T3 and VDA Score at T3.

Variable: PCA_T3_1

Label: Protean Career Attitudes Score at T3

Type: Numeric; Range = 1 to 5

Algorithm: PCA_T3_1 = MEAN (SDA_T3_1, VDA_T3_1)

If either SDA or VDA score is missing, then PCA_T3_1=Missing.

1.4.3.3. Change in Protean Career Attitudes (PCA) Score from Baseline to Month 3 Follow-Up (T1T3)

Description: Difference between protean career attitudes score at time point T3 (Month 3 follow-up) and time point T1 (Baseline)

Variable: PCA_T1T3_1

Label: Change in Protean Career Attitudes Score from T1 to T3 (T3-T1)

Type: Numeric; Range = -4 to 4

Algorithm: PCA_T1T3_1 = PCA_T3_1 – PCA_T1_1.

If PCA score at either time point is missing, then PCA_T1T3_1=Missing.

2. SECONDARY OUTCOMES

2.1. SELF-REPORTED EMPLOYMENT

The primary employment outcome is based on the change in the number of self-report hours worked per week from T1 to T3.

2.1.1. Change in Self-Reported Hours Worked Per Week from Baseline to Month 3 Follow-Up (T1T3)

Description: Change in hours worked per week from Baseline to Month 3 follow-up (T1 to T3)

Variable: EMPHOUR_T1T3_1

Label: Change in Hours Worked per Week from T1 to T3 (T3-T1)

Type: Numeric; Range = -99 to 99

Algorithm: If BSL9 = 0 then BSL27 = 0
If EXQ9 = 0 then EXQ27 = 0
EMPHOUR_T1T3_1 = EXQ27 – BSL27

If hours work per week at either time point is missing, then EMPHOUR_T1T3_1=Missing.

2.2. SELF-REPORTED SEXUAL RISK BEHAVIORS

2.2.1. Self-Reported Sexual Risk Behavior at Baseline (T1)

Description: Sexual Risk behavior is measured using items 239 through 244 from the BSL Questionnaire. Responses for each question are either Yes (1), No (0) or Missing (.). Risk Behavior is defined as the mean of responses to the risk behavior questions.

Variable: RISK_T1_1

Label: Self-Reported Sexual Risk Behavior at T1

Type: Numeric; Range = 0 to 1

Algorithm: RISK_T1_1 = MEAN (BSL239, BSL240, BSL241, BSL242, BSL243, BSL244)

If responses for four or more individual risk behavior questions are missing, then RISK_T1_1 = Missing. Otherwise, calculate the mean of non-missing responses.

2.2.2. Self-Reported Sexual Risk Behavior at Baseline (T3)

Description: Sexual Risk behavior is measured using items 239 through 244 from the EXQ Questionnaire. Responses for each question are either Yes (1), No (0) or Missing (.). Risk Behavior is as the mean of responses to the risk behavior questions.

Variable: RISK_T3_1

Label: Self-Reported Sexual Risk Behavior at T3

Type: Numeric; Range = 0 to 1

Algorithm: RISK_T3_1 = MEAN (EXQ239, EXQ240, EXQ241, EXQ242, EXQ243, EXQ244)

If responses for four or more individual risk behavior questions are missing, then RISK_T3_1 = Missing. Otherwise, calculate the mean of non-missing responses.

2.2.3. Change in Self-Reported Risk Behavior from Baseline to Month 3 Follow-Up (T1T3)

Description: Change in Self-Reported Risk Behavior of a participant from Baseline to month 3 follow-up (T1 to T3)

Variable: RISK_T1T3_1

Label: Change in Self-Reported Sexual Risk Behavior from T1 to T3 (T3-T1)

Type: Numeric; Range = -1 to 1

Algorithm: RISK_T1T3_1 = RISK_T3_1 – RISK_T1_1.

If risk behavior at either time point is missing, then RISK_T1T3_1 = Missing.

2.3. CHLAMYDIA INFECTIONS:

Chlamydia will be assessed at T1 (Baseline) and T3 (3-month follow-up) using urine, anal, and oral sample tests.

2.3.1. Chlamydia Result at Baseline (T1)

2.3.1.1. Chlamydia Result based on Oral Sample at T1

Description: The oral sample collection status is recorded in item 10a of the Biospecimen Collection (BIC1) form and the oral swab Chlamydia result is recorded in item 1a of the Biospecimen Results (BLR1) Form for Baseline (T1).

Variable: CH_ORAL_T1_1

Label: Assessment of Chlamydia using an Oral Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC10a = 1 then CH_ORAL_T1_1 = [BLR1] BLR1a
Else if [BIC1] BIC10a=1 and [BLR1] BLR1a=. then CH_ORAL_T1_1 = .U
Else if [BIC1] BIC10a=0 then CH_ORAL_T1_1 = .N
Else if [BIC1] BIC10a=9 then CH_ORAL_T1_1 = .R
Else if [BIC1] BIC10a=. then CH_ORAL_T1_1 = .

2.3.1.2. Chlamydia Result based on Anal Sample at T1

Description: The anal sample collection status is recorded in item 11a of the BIC1 form and the anal swab Chlamydia result is recorded in item 2a of the BLR1 Form for Baseline (T1).

Variable: CH_ANAL_T1_1

Label: Assessment of Chlamydia using an Anal Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC11a = 1 then CH_ANAL_T1_1 = [BLR1] BLR2a
Else if [BIC1] BIC11a=1 and [BLR1] BLR2a=. then CH_ANAL_T1_1 = .U
Else if [BIC1] BIC11a=0 then ANAL_CH_T1_1 = .N
Else if [BIC1] BIC11a=9 then ANAL_CH_T1_1 = .R
Else if [BIC1] BIC11a=. then ANAL_CH_T1_1 = .

2.3.1.3. Chlamydia Result based on Urine Sample at T1

Description: The urine sample collection status is recorded in item 12a of BIC1 form and the urine Chlamydia result is recorded in item 3a of BLR1 Form for Baseline (T1).

Variable: CH_URINE_T1_1

Label: Assessment of Chlamydia using a Urine Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC12a = 1 then CH_URINE_T1_1 = [BLR1] BLR3a
Else if [BIC1] BIC12a=1 and [BLR1] BLR3a=. then CH_URINE_T1_1 = .U

Else if [BIC1] BIC12a=0 then CH_URINE_T1_1 = .N
Else if [BIC1] BIC12a=9 then CH_URINE_T1_1 = .R
Else if [BIC1] BIC12a=. then CH_URINE_T1_1 = .

2.3.2. Chlamydia Result at Month 3 Follow-Up (T3)

2.3.2.1. Chlamydia Result based on Oral Sample at T3

Description: The oral sample collection status is recorded in item 10a of the Biospecimen Collection (BIC2) form and the oral swab Chlamydia result is recorded in item 1a of the Biospecimen Results (BLR2) Form for 3-Month Follow-up (T3).

Variable: CH_ORAL_T3_1

Label: Assessment of Chlamydia using an Oral Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC10a = 1 then CH_ORAL_T3_1 = [BLR2] BLR1a
Else if [BIC2] BIC10a=1 and [BLR2] BLR1a=. then CH_ORAL_T3_1 = .U
Else if [BIC2] BIC10a=0 then CH_ORAL_T3_1 = .N
Else if [BIC2] BIC10a=9 then CH_ORAL_T3_1 = .R
Else if [BIC2] BIC10a=. then CH_ORAL_T3_1 = .

2.3.2.2. Chlamydia Result based on Anal Sample at T3

Description: The anal sample collection status is recorded in item 11a of the BIC2 form and the anal swab Chlamydia result is recorded in item 2a of the BLR2 Form for the Month 3 follow-up (T3).

Variable: CH_ANAL_T3_1

Label: Assessment of Chlamydia using an Anal Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC11a = 1 then CH_ANAL_T3_1 = [BLR2] BLR2a
Else if [BIC2] BIC11a=1 and [BLR2] BLR2a=. then CH_ANAL_T3_1 = .U
Else if [BIC2] BIC11a=0 then CH_ANAL_T3_1 = .N
Else if [BIC2] BIC11a=9 then CH_ANAL_T3_1 = .R
Else if [BIC2] BIC11a=. then CH_ANAL_T3_1 = .

2.3.2.3. Chlamydia Result based on Urine Sample at T3

Description: The urine sample collection status is recorded in item 12a of BIC2 form and the urine Chlamydia result is recorded in item 3a of BLR2 Form for Month 3 follow-up (T3).

Variable: CH_URINE_T3_1

Label: Assessment of Chlamydia using a Urine Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC12a = 1 then CH_URINE_T3_1 = [BLR2] BLR3a
Else if [BIC2] BIC12a=1 and [BLR2] BLR3a=. then CH_URINE_T3_1 = .U
Else if [BIC2] BIC12a=0 then CH_URINE_T3_1 = .N
Else if [BIC2] BIC12a=9 then CH_URINE_T3_1 = .R
Else if [BIC2] BIC12a=. then CH_URINE_T3_1 = .

2.3.3. Change in Chlamydia Result from Baseline to Month 3 Follow-Up (T1T3)

2.3.3.1. Change in Chlamydia Result based on Oral Samples at T1T3

Description: Change in Chlamydia oral sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: CH_ORAL_T1T3_1

Label: Change in Chlamydia Oral Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Oral Result, -1=Positive to Negative

Algorithm: CH_ORAL_T1T3_1 = CH_ORAL_T3_1 – CH_ORAL_T1_1

If measurement at either time point is missing, then CH_ORAL_T1T3_1 = missing.

2.3.3.2. Change in Chlamydia Result based on Anal Samples at T1T3

Description: Change in Chlamydia anal sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: CH_ANAL_T1T3_1

Label: Change in Chlamydia Anal Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Oral Result,

-1=Positive to Negative

Algorithm: CH_ANAL_T1T3_1 = CH_ANAL_T3_1 – CH_ANAL_T1_1

If measurement at either time point is missing, then CH_ANAL_T1T3_1 = missing.

2.3.3.3. Change in Chlamydia Result based on Urine Samples at T1T3

Description: Change in Chlamydia urine sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: CH_URINE_T1T3_1

Label: Change in Chlamydia Urine Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Oral Result, -1=Positive to Negative

Algorithm: CH_URINE_T1T3_1 = CH_URINE_T3_1 – CH_URINE_T1_1

If measurement at either time point is missing, then CH_URINE_T1T3_1 = missing.

2.4. GONORRHEA INFECTIONS:

Gonorrhea will be assessed at T1 (Baseline) and T3 (3-Month follow-up) using urine, anal, and oral sample tests.

2.4.1. Gonorrhea Result at Baseline (T1)

2.4.1.1. Gonorrhea Result based on Oral Sample at T1

Description: The oral sample collection status is recorded in item 10a of the BIC1 form and the oral swab Gonorrhea result is recorded in item 1b of the BLR1 Form for Baseline (T1).

Variable: GN_ORAL_T1_1

Label: Assessment of Gonorrhea using an Oral Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC10a = 1 then GN_ORAL_T1_1 = [BLR1] BLR1b
Else if [BIC1] BIC10a=1 and [BLR1] BLR1b=. then GN_ORAL_T1_1 = .U
Else if [BIC1] BIC10a=0 then GN_ORAL_T1_1 = .N
Else if [BIC1] BIC10a=9 then GN_ORAL_T1_1 = .R
Else if [BIC1] BIC10a=. then GN_ORAL_T1_1 = .

2.4.1.2. Gonorrhea Result based on Anal Sample at T1

Description: The anal sample collection status is recorded in item 11a of the BIC1 form and the anal swab Gonorrhea result is recorded in item 2b of the BLR1 Form for Baseline (T1).

Variable: GN_ANAL_T1_1

Label: Assessment of Gonorrhea using an Anal Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC11a = 1 then GN_ANAL_T1_1 = [BLR1] BLR2b
Else if [BIC1] BIC11a=1 and [BLR1] BLR2b=. then GN_ANAL_T1_1 = .U
Else if [BIC1] BIC11a=0 then GN_ANAL_T1_1 = .N
Else if [BIC1] BIC11a=9 then GN_ANAL_T1_1 = .R
Else if [BIC1] BIC11a=. then GN_ANAL_T1_1 = .

2.4.1.3. Gonorrhea Result based on Urine Sample at T1

Description: The urine sample collection status is recorded in item 12a of BIC1 form and the urine Gonorrhea result is recorded in item 3b of BLR1 Form for Baseline (T1).

Variable: GN_URINE_T1_1

Label: Assessment of Gonorrhea using a Urine Test at T1

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC1] BIC12a = 1 then GN_URINE_T1_1 = [BLR1] BLR3b
Else if [BIC1] BIC12a=1 and [BLR1] BLR3b=. then GN_URINE_T1_1 = .U
Else if [BIC1] BIC12a=0 then GN_URINE_T1_1 = .N
Else if [BIC1] BIC12a=9 then GN_URINE_T1_1 = .R
Else if [BIC1] BIC12a=. then GN_URINE_T1_1 = .

2.4.2. Gonorrhea Result at Month 3 Follow-Up (T3)

2.4.2.1. Gonorrhea Result based on Oral Sample at T3

Description: The oral sample collection status is recorded in item 10a of the BIC2 form and the oral swab Gonorrhea result is recorded in item 1b of the BLR2 Form for 3-Month follow-up (T3).

Variable: GN_ORAL_T3_1

Label: Assessment of Gonorrhea using an Oral Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC10a = 1 then GN_ORAL_T3_1 = [BLR2] BLR1b
Else if [BIC2] BIC10a=1 and [BLR2] BLR1b=. then GN_ORAL_T3_1 = .U
Else if [BIC2] BIC10a=0 then GN_ORAL_T3_1 = .N
Else if [BIC2] BIC10a=9 then GN_ORAL_T3_1 = .R
Else if [BIC2] BIC10a=. then GN_ORAL_T3_1 = .

2.4.2.2. Gonorrhea Result based on Anal Sample at T3

Description: The anal sample collection status is recorded in item 11a of the BIC2 form and the anal swab Gonorrhea result is recorded in item 2b of the BLR2 Form for the Month 3 follow-up (T3).

Variable: GN_ANAL_T3_1

Label: Assessment of Gonorrhea using an Anal Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC11a = 1 then GN_ANAL_T3_1 = [BLR2] BLR2b
Else if [BIC2] BIC11a=1 and [BLR2] BLR2b=. then GN_ANAL_T3_1 = .U
Else if [BIC2] BIC11a=0 then GN_ANAL_T3_1 = .N
Else if [BIC2] BIC11a=9 then GN_ANAL_T3_1 = .R
Else if [BIC2] BIC11a=. then GN_ANAL_T3_1 = .

2.4.2.3. Gonorrhea Result based on Urine Sample at T3

Description: The urine sample collection status is recorded in item 12a of BIC2 form and the urine Gonorrhea result is recorded in item 3b of BLR2 Form for Month 3 follow-up (T3).

Variable: GN_URINE_T3_1

Label: Assessment of Gonorrhea using a Urine Test T3

Type: Numeric; Format: 1=Positive, 0=Negative, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC12a = 1 then GN_URINE_T3_1 = [BLR2] BLR3b
Else if [BIC2] BIC12a=1 and [BLR2] BLR3b=. then GN_URINE_T3_1 = .U
Else if [BIC2] BIC12a=0 then GN_URINE_T3_1 = .N

Else if [BIC2] BIC12a=9 then GN_URINE_T3_1 = .R
Else if [BIC2] BIC12a=. then GN_URINE_T3_1 = .

2.4.3. Change in Gonorrhea Result from Baseline to Month 3 Follow-Up (T1T3)

2.4.3.1. Change in Gonorrhea Result based on Oral Samples at T1T3

Description: Change in Gonorrhea oral sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: GN_ORAL_T1T3_1

Label: Change in Gonorrhea Oral Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Oral Result, -1=Positive to Negative

Algorithm: GN_ORAL_T1T3_1 = GN_ORAL_T3_1 – GN_ORAL_T1_1

If measurement at either time point is missing, then GN_ORAL_T1T3_1 = missing.

2.4.3.2. Change in Gonorrhea Result based on Anal Samples at T1T3

Description: Change in Gonorrhea anal sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: GN_ANAL_T1T3_1

Label: Change in Gonorrhea Anal Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea Anal Result, -1=Positive to Negative

Algorithm: GN_ANAL_T1T3_1 = GN_ANAL_T3_1 – GN_ANAL_T1_1

If measurement at either time point is missing, then GN_ANAL_T1T3_1 = missing.

2.4.3.3. Change in Gonorrhea Result based on Urine Samples at T1T3

Description: Change in Gonorrhea urine sample result of a participant from Baseline to Month 3 follow-up (T1 to T3)

Variable: GN_URINE_T1T3_1

Label: Change in Gonorrhea Urine Sample Result from T1 to T3 (T3-T1)

Type: Numeric; Format: 1=Negative to Positive, 0=No Change in Gonorrhea urine result, -1=Positive to Negative

Algorithm: GN_URINE_T1T3_1 = GN_URINE_T3_1 – GN_URINE_T1_1

If measurement at either time point is missing, then GN_URINE_T1T3_1 = missing.

2.5. REACTIVE HIV TEST

Description: Testing for HIV is conducted at Baseline (T1) and Month 3 follow-up (T3) and indicates whether or not the test result was reactive or non-reactive. The reactive HIV testing result for T3 is recorded in item 1a of the BIC2 form.

Variable: HIVREAC_T3_1

Label: Reactive HIV Test Result at T3.

Type: Numeric; Format: 0=Non-Reactive, 1=Reactive, .U=Unknown, .N=Not Collected, .R=Refused, .=Missing

Algorithm: If [BIC2] BIC1=1 then HIVREAC_T3_1= [BIC2] BIC1a
Else if [BIC2] BIC1=1 and [BIC2] BIC1a=. then HIVREAC_T3_1=.U
Else if [BIC2] BIC1=0 then HIVREAC_T3_1_1 = .N
Else if [BIC2] BIC1=9 and [BIC2] BIC1a=9 then HIVREAC_T3_1=.R
Else if [BIC2] BIC1=. and [BIC2] BIC1a=. then HIVREAC_T3_1=.