AVANCE Houston FRAMEWorks Program Evaluation

Statistical Analysis Plan

2/6/2024

Clinicaltrials.gov ID: NCT05261802

IV. Data Analysis

A. Data analysis

The local evaluators will run linear or logistic regression analyses to assess changes in participant outcomes after FRAMEWorks Program participation. Survey items will be explored individually and as part of constructs (e.g., parenting behaviors) that have been validated by confirmatory factor analysis. Relevant co-variates will be included in the models as controls. The evaluation team will continue to work with the program's ETAP to refine analytical methods.

To answer the ancillary question of potential differences between participants who participate virtually vs. in person, the local evaluators also plan to conduct an exploratory analysis of the moderating effect of delivery format.

Data analysis

Overview: The primary analysis for this descriptive study is to assess changes in outcomes presented in Table 2 after participation in the FRAMEWorks Program primary services. Changes in attitudes and behaviors are assessed by comparing participant responses on the OLLE and nFORM Healthy Marriage Adult Program Survey pre-surveys to participant responses on program exit surveys (OLLE and nFORM) and the OLLE 1-year follow-up survey.

Analysis begins by creating indices for constructs that will serve as the dependent variables. Constructs comprise the relevant behavioral or attitudinal survey items on the nFORM and OLLE surveys. All constructs have been confirmed with psychometric evidence derived from confirmatory factor analysis (CFA) or have already been supported by evidence of reliability and validity. Indices will be created by adding together the response codes for each of the scaled items within a given construct.

In addition to changes in the outcomes outlined above, exploratory analyses of differences in program format (weekly workshops compared to weekend retreat), virtual vs in-person, gender, and dosage are possible.

Step 1: Index scores will be compared between a participant's pre-survey and post-survey responses, and again between a participant's pre-survey and follow-up survey responses. Paired statistical tests will be used to determine if changes in outcomes between waves of data collection are significant ($p < 0.05$). The primary change of interest in this study is the difference between pre-survey responses and follow-up survey responses to see if changes persist long after program participation.

Step 2: To further explore how individual characteristics (e.g., gender), programmatic differences (e.g., virtual compared to in-person workshop delivery; weekly compared to weekend schedule format), and program dosage (e.g., number of primary hours received) may interact with program participation to create change in the outcomes of interest, a secondary analysis will be done using regression modeling. The data will be examined before analysis to determine if linear regression is appropriate. Statistical significance will be measured at the $p < 0.05$ level. The independent variables for this analysis will be a dosage measure quantifying the number of primary programming hours received and dummy variables for delivery method. Self-reported demographic characteristics will be taken from the nFORM Applicant Characteristics Survey (ACS) to be included as co-variates in the model. This will be an exploratory analysis and is not attempting to make a causal inference about the impact of program dosage or delivery method.

IRB/protection of human subjects

MER has received Institutional Review Board (IRB) approval from Solutions IRB to conduct this descriptive evaluation.

Solutions IRB, a private commercial Association for the Accreditation of Human Research Protection Programs Inc. (AAHRPP) fully accredited Institutional Review Board, will ensure that this study is approved before any research activities take place. MER has had 14 research studies approved by Solutions IRB over the past four years, has completed over 15 annual check-in reports, and has submitted timely amendments when changes to studies needed to take effect.

All submissions are completed online, so turnaround for a new study approval is between 24 to 72 hours, though the full approval process can take approximately one to two weeks depending on the number of questions and requested revisions that the IRB makes. In the IRB application submission, we will include descriptions of project staff, locations of study sites, the funding source, incentives, summary of activities, participant population, recruitment plans, risks and benefits, confidentiality of data, and the informed consent process along with all materials to be used in the study such as participant forms and surveys.

See Appendix C for Federal Wide Assurance.

Data

Table VC.1: Description of Databases

Database Name	*Data Entered*	*Process for Data Entry*
nFORM	Outcome and program performance measurement data	Entered directly by participants and FRAMEWorks Program staff
Qualtrics	Local evaluation data, participant outcomes	Entered directly by participants and by MER evaluation staff

Table VC.2: Data reporting, linking, and transfer

Database Name	*Ability to Export Individual Reports?*	*What identifying information is available to facilitate linking to other data sources?*
nFORM	Yes	nFORM Client ID, Name, DOB
Qualtrics	Yes	nFORM Client ID, Name, DOB