

Goodwill of Central Texas: Fatherhood Works Healthy Marriage and Responsible Fatherhood Program Evaluation

Statistical Analysis Plan

Clinicaltrials.gov ID: NCT05292963

1. Data Analysis

Briefly describe the planned approach for data analysis. If an impact analysis is proposed, name the key dependent and independent variables, and describe any methods to minimize Type I error (i.e., finding positive impacts by chance) such as limiting the number of impacts to be analyzed and/or multiple comparison correction. Describe proposed approach(es) for addressing missing data.

Overview:

The primary analysis for this descriptive study is to assess changes in the primary and secondary outcomes presented in Table 1.1 1 year after enrollment in the Fatherhood Works Program primary services. Changes in attitudes and behaviors are assessed by comparing participant responses on the nFORM Community Fathers Entrance Survey to participant responses on the OLLE 1-year follow-up survey.

Identify study sample

The study sample includes participants who: 1) gave recorded informed consent to be part of the study, and 2) took the nFORM Community Fathers Entrance Survey, the post survey (for the parenting attitude measure), and OLLE 1-year follow-up survey (for behavioral measures and employment attitude measure). The CONSORT diagram in Appendix B shows exclusion criteria and the anticipated size of the overall study sample. The analytic sample for particular outcome measures will vary based on missing data.

Defining Analysis Measures

For each outcome construct, we have identified the relevant measures from nFORM and the OLLE Survey that are theoretically aligned with that construct. We will generate a correlation matrix between items in a given construct to ensure that theoretically related items are also empirically related in our data set. Items that are not strongly correlated with other items in a construct will be removed as necessary. Factor analysis will be used to ensure that all construct items hang together (using an alpha of 0.7 or higher as the threshold).-

Once we are confident that all of the items align with a given construct, we will create a composite measure by taking an average of the scores on each non-missing item in the construct. The measure definition matrix below provides information on each proposed outcome. For composite measures, a change score will be calculated between a participant's pre-program composite score and post-program composite score for parenting attitude measure, and between pre-program composite score and 1-year follow-up composite score for all other measures. For standalone

survey items, a change score will be calculated between a participant's pre-survey and 1-year follow-up survey responses. -

For the sake of consistency and simplicity, parenting and co-parenting analyses will use a participant's youngest child as the focal child.

Measure	Sample	Variable Type	Data source(s)	Variable Name	Definition
Parenting relationship behaviors	Has at least one child age 24 or younger, saw child within past month	Categorical (range from 1 to 5 where 1 is never and 5 is every day or almost every day)	nFORM entrance, OLLE post 1-year follow-up	Par_Beh	Average of 7 survey items that relate to frequency of positive interactions with participant's youngest child.
Frequency of Contact	Has at least one child age 24 or younger	Categorical (Range from 1 to 4 where 1 is every day or almost every day and 4 is never)	nFORM entrance, OLLE post 1-year follow-up	Reach_Out	Reported number of hours per day (excluding sleeping) that parent usually spent with their youngest child
Parenting Attitudes	Has at least one child age 24 or younger	Continuous (range from 1 to 5 where 1 is strongly disagree and 5 is strongly agree)	nFORM entrance, OLLE post survey	Par_Att	Average of seven survey items that relate to frequency of key parenting attitudes.
Co-parenting relationship behaviors	Has at least one child age 24 or younger	Continuous (range from 1 to 5 where 1 is strongly disagree and 5 is strongly agree)	nFORM entrance, OLLE post 1-year follow-up	Copar_Beh	Average of 11 survey items that relate to positive interactions with the mother of participant's youngest child

Employment Attitudes	All study participants	Continuous(range from 1 to 5 where 1 is strongly disagree and 5 is strongly agree)	OLLE pre-survey, OLLE post 1-year follow-up	Emp_Att	Two independent items that relate to frequency of key attitudes related to acquiring a job and providing for a family .
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Handling missing data

Outcomes

When creating the composite measures for co-parenting and parenting relationships, we will create a composite score by taking the average of multiple individual items. For these measures, our current plan is to use 20% as a threshold for allowable missing items, based on guidance from evaluation technical assistance resources. This plan is contingent on the final distribution of missing data in our data set. We will not be imputing truly missing values for outcomes. To create a construct score, the average will divide by the number of non-missing values in the construct.

Participants who have not seen their child within the past month will have their parenting behavior responses set to “Never” (1) and will be included in the analytic sample for that outcome.

For outcomes that use single survey items, participants who do not respond to the item on either the pre-survey or follow-up survey will be excluded from the analytic sample for that outcome.

Missing data for the implementation outcomes could happen as a result of programmatic data entry issues. For the sake of this evaluation, we assume that any primary or support services received by a participant are being accurately logged into nFORM, so a lack of documented attendance, service contacts, referrals, etc. is indicative of lack of services (i.e., a participant not receiving the program components as intended).

Assessing non-response bias

We will conduct response rate analysis for each primary outcome of interest to assess non-response bias and adjust for threats to internal validity. Using data from the Applicant

Characteristics Survey, we will look at demographics (race, ethnicity, age, education level) and primary reason for joining the program among participants who fall into each of the following categories: 1) non-respondents who answered no surveys after the ACS, 2) respondents who completed the pre-survey only, 3) respondents who completed the follow-up survey only, and 4) respondents who completed both a pre- and follow-up survey (complete case).

Analytic approach

The main goal of this descriptive study is to assess pre-post change scores in the attitudinal outcomes listed above among program participants before (pre) and immediately following program completion, and in the behavioral outcomes listed above among program participants before and 1 year after enrolling in primary workshops. We will use paired sample t-tests to assess the magnitude and significance of changes among program participants in the analytic sample for each outcome. We will adjust our p-values for multiple hypothesis testing and report the adjusted p-values in the appendix of the final report.

For the implementation analysis, program fidelity will be descriptively reported by the percentage of enrolled participants who receive: 1) any primary workshops, 2) employment supports, 3) substantive service contacts, 4) referrals. The program aims to provide all participants each of these four program components, so the percentage of participants who receive each of these will be compared to the 100% benchmark. Number of substantive service contacts per participant will also be compared to the benchmark of 8 SSCs set by OFA for FIRE grantees.

Dosage will be measured by percent of target primary workshops participants attend on average (using 90% as a benchmark), and categories of attendance (initial, halfway, 90%, 100%) will be reported and compared to targets established by the program and reported on page 3 above. Exploratory analysis will examine how dosage varies by workshop characteristics (e.g., virtual vs in-person) and participant characteristics (e.g., age, employment status, relationship status).

2. Data Archiving and Transfer

Briefly describe the planned approach data arching and transfer by addressing questions below.

What procedures and parameters are established for all aspects of data/information collection necessary to support archiving data collected as part of the evaluation?

Examples include informed consent, data maintenance, de-identifying data procedures.

All program data, including consent forms, service data, and surveys will be maintained securely during the project period. Once the evaluation / research period is over and analysis of the data and reporting is complete, MER will de-identify the data and make them available for sharing with other researchers or on federal data sites that are appropriate and exist at that time. To facilitate this, MER will develop and implement a Data Archiving plan for this project (as it does for all such major evaluation efforts). MER's Data Archiving plan / process includes the following steps:

1. Inventorying and determining which data must be archived, and which data will not be archived or shared (such as personally identifiable information of participants)
2. Ensuring that all required data elements are maintained in a way that is compliant with OFA and OPRE guidance and regulations and best practices. This includes the creation of supporting documentation such as a code book which makes the data useable by future researchers.
3. Develop an all-inclusive archive policy for the specific data needs, which ensures that archiving is achievable and manageable, which will include the specifics on the duration of data storage (5 years), benchmarks for archiving data, the variety of media to be used for storage – both Dropbox long term storage and physical storage on secured flash drives, and rules for who will have access to the data, controlled by Dropbox controls and physical storage in a locked and fireproof storage facility.
4. Proactive protection of the data archive's integrity – by selection of the Dropbox Enterprise company to warehouse the data – using the protections described above, including the active scanning of stored data. Dropbox also includes search and discovery function, automated back-up, and total encryption.

Describe how the collection methods for all types of proposed data collection will support the archiving and transfer of each type.

Because the data collected will be combined from a secure data-based system into a tab delimited data sheet that can be exported into a variety of formats including Excel, these systems support the data

	archiving function and facilitate the sharing of data when appropriate.
<p>How will consent form language represent plans to store data for sharing and/or transferring to other researchers?</p>	<p>The MER consent forms and processes clearly explain the use and long-term storage of data and the protection of personal and identifiable information to participants (and the de-identification of data kept long term).</p>
<p>Describe methods of data storage that will support archiving and/or transferring data.</p>	<p><i>MER's Data storage plan includes both physical and SAS (software as service) processes for long-term storage and transfer. As the data set is being built, Qualtrics and Dropbox will be the primary and redundant systems for data storage. Once all the data has been collected and the data set has been securely and completely de-identified, all data will be removed from Qualtrics, and a long-term storage file with limited access will be maintained on Dropbox. In addition, physical download of the data will be made using multiple formats and copies (flash drive and CD or other media available at the time), and these data will be stored securely in two locked locations – a bank vault and MER headquarters protected in a safe behind multiple locks and limited access.</i></p> <p><i>When transfer is appropriate, either a secure internet-based file transfer can be used, or a delivery of a physically stored data set can be accomplished.</i></p>
<p>Explain how data and analyses file construction and documentation will support data archiving and/or transferring.</p>	<p><i>As part of the data analysis and clean up, a codebook will be constructed that describes the data fields and how they were collected or constructed. Supporting documentation will be stored with the data sets for easy transfer when appropriate.</i></p>