TYRO Champion Dads

Statistical Analysis Plan

12/9/2024

ClinicialtrialI.gov ID:
NCT05256992

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.

Identify impact study sample

The impact study sample includes participants who: 1) were eligible to be randomized based, 2) gave recorded informed consent to be part of the study and randomly assigned to a treatment group, and 3) took both an entrance and exit and/or follow-up survey. The CONSORT diagram in Appendix A shows exclusion criteria and the anticipated size of the overall impact study sample, which we anticipate to differ for attitudinal items that will use wave 2 data vs behavioral questions that will use wave 3 data. 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 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 measure.

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
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 follow-up	Copar_Beh	Average of 11 survey items that relate to positive interactions with the mother of participant's youngest child

Parenting relationship behaviors	Has at least one child age 24 or younger, saw child within past month	Continuous (range from 1 to 5 where 1 is never and 5 is every day or almost every day)	nFORM entrance, OLLE follow-up	Par_Beh	Average of 10 to 11 survey items (depending on child age) that relate to frequency of positive interactions with participant's youngest child
Parenting relationship attitudes	Has at least one child age 24 or younger, saw child within past month	Continuous (range from 1 to 5 where 1 is always and 5 is never)	nFORM entrance, nFORM exit	Par_Att	Average of 6 survey items that relate to frequency of feelings about participant's youngest child
Parenting relationship behaviors	Has at least one child age 24 or younger, saw child within past month	Continuous (range from 1 to 5 where 1 is never and 5 is every day or almost every day)	nFORM entrance, OLLE follow-up	Parent_Fight	Reported frequency of fighting with child
Partner relationship behaviors	All survey respondents	Continuous (range from 1 to 5 where 1 is never and 5 is always)	OLLE pre-survey, OLLE post-survey, OLLE follow-up	Partner_Fight	Reported frequency of fighting with partner
Partner relationship behaviors	All survey respondents	Continuous (range from 1 to 5 where 1 is never and 5 is always)	OLLE pre-survey, OLLE post-survey, OLLE follow-up	Partner_Disagree	Average of 7 survey items related to frequency of disagreement with partner on different topics

Analytic approach

The main goal of this impact study is to assess the impact of the addition of the Ray of Hope curriculum intervention on participant attitudinal outcomes immediately following program completion, and behavioral outcomes six months after program enrollment, as compared to the impact of standard TCD services alone.

Participation benefits are defined by the primary and secondary outcomes presented earlier in the theory of change logic model and with research questions and hypotheses. Impact estimates are based on participant responses to the OLLE Follow-up Survey across randomly assigned study groups to compare primary and secondary outcomes between them 6-months after TCD Project enrollment. More positive outcomes for the treatment group will be attributed to the intervention given that other TCD services are delivered in the same ways to both study groups under a shared condition.

Steps begin by creating constructs that serve as the dependent variables used to model comparisons of primary outcomes—parent, co-parent, and partner relationship behaviors—and secondary outcomes—parenting attitudes. Constructs are comprised of the relevant survey items on the nFORM Community Fathers Survey and the OLLE Survey. Constructs are confirmed with psychometric evidence derived from confirmatory factor analysis (CFA), except when they are already supported by evidence of reliability and validity or based on one item that is sufficiently broad to investigate an outcome. Next, results from baseline equivalency analyses identify co-variates to specify in the model that control for any detected differences in participant characteristics or developmental starting points in healthy family relationships and economic stability. Model results are interpreted to determine if assignment to the treatment group positively predicts ($p < .05$) more improved outcomes than the control group 6-months after enrollment into TCD services for behavior outcomes and immediately following program completion for attitudinal outcomes.

Finally, type 1 and type 2 error are controlled in this study. Type I error is the rejection of a true null hypothesis (also known as a "false positive" finding or conclusion; example: "an innocent person is convicted"). We control for type 1 error in two ways. First, alpha levels are set at .05, so only 1 in 20 findings should result in a false positive, and we plan to use the Bonferroni correction method to adjust for multiple hypothesis tests. Second, research questions are limited to modeling six outcomes. Type II error is the non-rejection of a false null hypothesis (also known as a "false negative" finding or conclusion; example: "a guilty person is not convicted"). We control for Type 2 error by having sufficient power to detect small or nearly small minimum detectable effect sizes. (The estimated effect sizes are all almost small effects that would be detected, based on best practices outlined by Cohen (1988) of small effect sizes <0.02 and medium effect sizes <0.15.)

Chi-Square and 2-sample t-tests assess baseline equivalency of study groups by analyzing pre-survey responses to items that describe the characteristics of participants and their developmental starting points before receiving TCD services. Participant characteristics— such as demographics, family structure, and socioeconomic background—are reported on the nFORM ACS Survey. Developmental starting points refer to the attitudes and behavior exhibited before TCD participation and are reported on the nFORM Community Fathers Entrance Survey and OLLE Pre-survey. Chi-Square tests are run for

categorical and dichotomous variables, such as relationship status (e.g., married, single, divorced) or whether a participant reports having a savings account (i.e., yes/no). Two-sample t-tests are run for interval and continuous variables, such as the number of children in a household, or levels of agreement with healthy parenting attitudes. Any differences detected across study groups are incorporated into the model as co-variates.

Study group assignment (1=treatment, 0=control) is repeatedly regressed against the dependent variables to model comparisons of outcomes constructs between study groups (see the table below). Co-variates specified in the model will control for the influence of any significant baseline differences between study groups that were detected in the baseline equivalency analyses for demographics, family structure, socioeconomic background, and developmental starting points.

Procedures to run the linear regression model rely on standard regression to model the influence of study group assignment on dependent variables. All dependent variables are continuous, such as when participants report how many hours they spend with their child or respond to multiple items in a scaled construct by indicating levels of agreement with statements about key parent attitudes.

Benefits of the Ray of Hope curriculum will confirm hypotheses if respondents assigned to the treatment group report greater improvements in outcomes ($p<.05$) than those in the control group for each outcome measure identified above.

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.

Handling missing data

Outcomes

When creating the composite measures for our behavior and attitude outcomes, 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. If participants have more than 20% of items missing for a given construct, the respondent will be assigned a missing value for that construct and will be excluded from the analytic sample for that outcome. 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.

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

Data for the implementation outcomes could be missing 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 a pre-survey only, and 3) respondents who completed both a pre- and follow-up survey (complete case). We will also look for differential response rates between the standard/control and enhanced/treatment groups.