

An Internet Based Adaptation of a Divorce Intervention Beginnings Program for
Divorced Parents

NCT05209932

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Study Protocol. The protocol is described as it was presented in the grant application. However, due to the COVID pandemic the trial was much more difficult to conduct than anticipated. In order to preserve our ability to implement the RCT, the scope of the trial was modified to have a reduced number of participants and to drop the follow-up assessment while preserving random assignment and responses from both children and parents. These changes were approved by our program officer. We also changed the comparison condition from an internet program comparison to a waitlist control condition because we felt that the latter is a more ecologically valid comparison.

Recruitment and Procedures. Qualtrics leading-edge sample acquisition technology will be used to recruit 360 parents from a nationally representative sample of divorced parents that includes the same percentages of ethnic groups as in the US Census data.

Initial sampling criteria will include: divorced, separated but never married, divorcing or separating; has one child or more between 6 and 18, and English speaking. As in our effectiveness trial, both mothers and fathers as well as separating parents who were never legally married will be eligible to participate. Parents who meet initial sampling criteria will be sent an email with further information about the study including a link to a video invitation to participate in the study. Parents will complete a web-based survey including questions about contact level with child/ren (to be eligible parents need to have a minimum amount of contact defined as at least three hours/week or at least one overnight every other week) and access to a computer with high-speed internet or a smart phone. We will receive a list with phone numbers and email addresses of parents who fully meet the above criteria and are interested in participating in the study. A research specialist will contact parents by phone to provide details of the study (e.g., random assignment, compensation), rescreen for eligibility and have parents complete a consent form using Konexx, a leading voice-recording product.

Parents with offspring ages 11 to 18 will be asked to provide permission for them to participate in assessments. Based on our previous randomized trials with divorced families, we anticipate there will be 1.5 children/family who are between 6 and 18 years old, giving a total of 540 children. We anticipate that 50% of the offspring will be 11 or older, giving a possible total of 270 adolescent reports.

Offspring ages 11-18 whose parents provide permission for them to participate in the assessments will be called by a research specialist who will explain the nature of their participation and have the adolescent complete one of two developmentally appropriate assent forms (11-13; 14-17) or consent (18) form using Konexx. After the consent/assent process has been completed, parents and youth will be emailed a web link to access the pretest. After this link is sent, parents and youth will receive up to three email reminders (every 2 days) about completing the pretest. The assessments will be 15 minutes in length and parents and youth will each receive \$30 electronic gift card for each assessment.

Immediately after completing the pretest, parents will be randomly assigned (block by gender and ethnicity) to the eNBP or to a waitlist comparison condition using a computerized program. Parents in the eNBP condition will be sent a link to eNBP and instructed to complete the program over the next 10 weeks. Parents in the WebC will be sent a link to the control web-site and will be instructed to use the material on the website over the next 10 weeks. To reduce attrition across assessments, contact efforts (e.g., address verification requests by email,

contact with non-responders by phone or letter) will be conducted every two months. Parents will receive a \$5 electronic gift card for providing address updates. Three months after the pretest, participants will be sent a link to the posttest assessment.

Phone calls will be made to non-responders. Six months after the posttest, participants will be sent a link to the 6-month follow-up assessment; phone calls will be made to non-responders. Upon completion of the 6-month follow-up survey, parents in the WebC will receive a link to access eNBP. Study procedures will be reviewed by the Quorum Institutional Review Board (IRB). Dr. Porter will develop and submit the IRB protocol, with significant input from Drs. Sandler and Wolchik.

Conditions. eNBP will consist of 10 modules that teach skills to increase positive family interactions, active listening skills, and effective discipline, and decrease exposure to interparental conflict.

Parents in the WebC will be provided with a link to a website that has been recommended by authoritative experts.

C3.33 Measures. Parents and youth ages 11 to 18 will complete measures of parenting, conflict and children's outcomes. Parents will answer questions about parenting and children's outcomes for each of their children ages 6-18. The timeframe for all measures will be the last month. We will use age and gender norms for the BPM. We selected measures that have been shown to be sensitive to program effects, are appropriate for children 6 to 18, are equivalent across ethnic groups, and have adequate reliability and validity. When possible, we will obtain parent and child report of a construct.

Data Analyses. All data will be managed and processed by project staff to ensure that the data collected are of the highest quality. Block randomization, which improves face validity, precision, and power, will be conducted within parent gender and ethnicity using a random number generator. Power is based on the MPlus simulation program or Optimal Design using $\alpha = .05$ (two-tailed) and power $(1-\beta) = .80$. We will apply intent-to-treat analyses (i.e., including every family who is randomized) to examine program effects. We will perform sensitivity analyses to check the nonresponse mechanism and attrition analyses (i.e., comparing those who stay and those who leave across condition) on the baseline variables to understand the patterns of attrition and then use modern analytical strategies such as multiple imputation (MI) or full information maximum likelihood (FIML) for dealing with ignorable missing data (i.e., missing completely at random [MCAR] or missing at random [MAR]) or the selection model or the pattern mixture model to deal with nonignorable missing data (i.e., missing not completely at random [MNAR]). Thus, we will use the entire randomized sample for hypothesis testing. Confirmatory factor analyses (CFA) will test measurement models for the domains that involve multiple indicators or multiple informants. Such data reduction procedures will serve to reduce measurement errors and consolidate measures into key theoretical constructs. We will examine measurement equivalence across child age (e.g., 6-9, 10-18), gender, and ethnicity. Mplus¹³⁰ will be the primary statistical program for our analyses which can incorporate FIML and MI for handling missing data.

Outcome analyses. We will compare means across condition at post-test and 6-month follow-up using random effects or mixed effects analyses of covariance (ANCOVA) controlling for possible baseline differences. Clusters of children in the same family will be treated as random effects. The 6-month follow-up analyses will assess maintenance or an increase or decrease in effects over time. We will use all of the three assessments and conduct repeated measures random

effects model (i.e., time points nested in individuals and children nested in families) to evaluate the trajectory of program effects. Specifically, we will estimate whether individual trajectories vary from person to person and whether the inter-individual variation is systematically related to condition. In addition to main effects, we are interested in potential differential program effects across baseline conflict, parent gender and ethnicity and child age. Moderation will be tested using the condition by moderator interaction. For significant interactions, we will conduct simple effects analyses to probe the magnitude and direction of the program effects at different levels of the moderator. Depending on the intraclass correlation (ICC), we have power to detect a mean difference with a small effect for the full sample ($d = .25\text{-.29}$; $.36\text{-.41}$ for adolescents [10-18]). For the moderated effects, we have power to detect a small effect for the full sample ($R^2 = 2\%\text{-}3\%$; $4\%\text{-}5\%$ for adolescents [10-18]). Note that the interaction effects in randomized trials are in general small.

For models with limited power, we plan to use bootstrap methods, which improve precision of asymptotic approximations (e.g., confidence interval) or a Bayesian approach, which incorporates prior information to improve estimation, for hypothesis testing. For repeated measures, we have power to detect a small effect for the full sample (i.e., $d = .20\text{-.22}$; $.27\text{-.31}$ adolescents [10-18]). A simulation study shows that mixture modeling with repeated measures provides better power than the traditional ANCOVA.